UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF VERMONT

[UNDER SEAL], Plaintiffs, v. [UNDER SEAL], Defendants.	Case No: 2:22-cv-27 **COMPLAINT** **FILED IN CAMERA AND UNDER SEAL PURSUANT TO 31 U.S.C. § 3730(b)(2)**

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UNITED STATES DISTRICT COURT
DISTRICT OF VERMONT

UNITED STATES and the STATES of CALIFORNIA, COLORADO, CONNECTICUT, DELAWARE, FLORIDA, GEORGIA, HAWAII, ILLINOIS, INDIANA, IOWA, LOUISIANA, MARYLAND, MASSACHUSETTS, MICHIGAN, MINNESOTA, MISSOURI, NEVADA, NEW JERSEY, NEW MEXICO, NEW YORK, NORTH CAROLINA, OKLAHOMA, RHODE ISLAND, TENNESSEE, TEXAS, VERMONT, VIRGINIA, WASHINGTON, the DISTRICT OF COLUMBIA, and DOE STATES 1–20, *ex rel.* BARBARA BAY, Plaintiffs, v. CLINOVATIONS, a product line of THE ADVISORY BOARD; OPTIMIZERX CORPORATION; PDR, LLC, d/b/a CONNECTIVERX; POINT OF CARE PARTNERS; CHANGE HEALTHCARE INC. f/k/a CHANGE HEALTHCARE SOLUTIONS, LLC; GLAXOSMITHKLINE PLC; PFIZER, INC.; ALLSCRIPTS HEALTHCARE SOLUTIONS; EPIC SYSTEMS CORPORATION; and DOE DEFENDANTS 1-100, Defendants.	Case No: **COMPLAINT FOR VIOLATIONS OF THE FEDERAL FALSE CLAIMS ACT AND STATE FALSE CLAIMS ACTS** **FILED IN CAMERA AND UNDER SEAL PURSUANT TO 31 U.S.C. § 3730(b)(2)** **JURY TRIAL DEMANDED**

Qui tam plaintiff-relator Barbara Bay, on behalf of the United States, the States of California, Colorado, Connecticut, Delaware, Florida, Georgia, Hawaii, Illinois, Indiana, Iowa, Louisiana, Maryland, Massachusetts, Michigan, Minnesota, Montana, Nevada, New Jersey, New Mexico, New York, North Carolina, Oklahoma, Rhode Island, Tennessee, Texas, Vermont, Virginia, Washington, the District of Columbia, and Doe States 1–20 (collectively "the States"),

for their Complaint against defendants Clinovations, a product line of The Advisory Board, OptimizeRx Corporation, PDR, LLC, d/b/a ConnectiveRx, Point of Care Partners, Change Healthcare Inc. f/k/a Change Healthcare Solutions, LLC (collectively "Aggregator and Consultant Defendants"); GlaxoSmithKline plc, Pfizer, Inc., (collectively "Pharmaceutical Defendants"); AllScripts Healthcare Solutions and Epic Systems Corporation (collectively "EHR Defendants") and Doe Defendants 1-100, alleges as follows:

I. INTRODUCTION

1. This is an action to recover damages and civil penalties on behalf of the United States of America and the States arising from false and/or fraudulent statements, records, and claims made and caused to be made by defendants and/or their agents, employees and co-conspirators, in violation of the Federal Civil False Claims Act, 31 U.S.C. §§ 3729–33, as amended ("the FCA"), and the false claims acts of the States as set forth below.

2. This complaint alleges that Defendants have participated in illegal marketing campaigns to induce prescribing of prescription medication and vaccines paid for by federal health programs including Medicare and Medicaid. The illegal marketing campaigns violate the Anti-Kickback Statute ("AKS"), 42 U.S.C. §1320a-7(b)(b). The illegal conduct in violation of the AKS causes the submission of false claims for payment to federal health care programs in violation of the federal False Claims Act, 31 U.S.C. § 3729(a)(1)(A) and corresponding state False Claims Act statutes.

3. Under these marketing campaigns, the Pharmaceutical Company Defendants – GlaxoSmithKline (GSK) and Pfizer – have paid remuneration to the EHR Defendants, and other electronic health record (EHR) companies, to arrange for health care providers (HCPs) using the EHR systems to prescribe specific branded prescriptions drugs and vaccines marketed by the Pharmaceutical Company Defendants, including to federally-insured patients. These digital interventions are intended to, and have the effect of, influencing the physicians' clinical decision making in favor of prescribing the branded product being promoted precisely at the point the

health care provider refers the patient for treatment and prescribes prescription drugs for specific patients with specific medical conditions.

4. The Pharmaceutical Company Defendants pay remuneration to the EHR Defendants, and other EHR companies, with the assistance of intermediaries including Clinovations, a product line of The Advisory Board, OptimizeRx, ConnectiveRx, Point of Care Partners, Change Healthcare, and others, to obtain exclusive access for their branded pharmaceutical products within the clinical decision support tools and other digital interventions within the EHRs.

5. These digital marketing programs are designed to exclude competitor products, including generic products, from similar digital interventions at the point of clinical decision making and prescribing. The opportunity to exclude competitors is marketed as a valuable feature of the contractual relationships by the EHRs and intermediaries promising 100% "Share of Voice" to the branded pharmaceutical company.

6. Some of the EHR Defendants, including AllScripts, enter into direct contractual relationships with branded pharmaceutical companies to market prescription drugs for the pharmaceutical companies at the point of clinical decision making. EHR companies also contract with Pharmaceutical Company Defendants through so-called EHR aggregators (collectively known herein as EHR Aggregator and Consultant Defendants) that serve as "middle men." These aggregators and advisors arrange for the exchange of remuneration from the Defendant Pharmaceutical Companies in exchange for data from the EHR Defendants confirming that the digital interventions are achieving the anticipated return of investment by increasing prescriptions by health care providers for the branded drugs being promoted. This analysis is typically called a "script lift analysis."

7. Additional euphemisms are used to describe the digital interventions having achieved the recommended and desired "resolution" at the point of prescribing. Despite numerous references to disease education, the focus and goal of the digital marketing programs

is to have the EHRs arrange for referrals by providers of patients to their prescription drug medication and to increase utilization, specifically utilization of their specific branded drugs or vaccines rather than competitor drugs or vaccines.

8. Defendants Clinovations, a product line of The Advisory Board, OptimizeRx, ConnectiveRx, Change Healthcare, and Point of Care Partners, solicit and receive remuneration from the Defendant pharmaceutical companies as compensation for arranging for digital interventions within EHRs designed to induce providers to write prescriptions for Defendant Pharmaceutical Companies' prescription medications, including for federally-insured patients.

9. All participants in these schemes – Defendant Pharmaceutical Companies, Defendant EHRs, and Defendant Aggregators and Consultants - tout these programs as intended to "promote awareness" of best practices in clinical care for certain disease states and some as consistent with national clinical guidelines. But the design of the programs, and the deliverables associated with the underlying contracts, demonstrate that the intended purpose is to cause EHRs to utilize their unique influence over clinical decision making to arrange for health care providers to increase their prescriptions of particular branded pharmaceutical products (to the exclusion of competitor products or to prescribing no medication at all).

10. These digital marketing programs extend beyond what might appear to be akin to advertising, such as banner and pop-up ads and hyperlinks to branded pharmaceutical landing pages. These promotional campaigns are designed to provide the Defendant Pharmaceutical Companies with unique and exclusive access to prescribers within the context of specific patient encounters and at the very moment they are making prescribing decisions.

11. As described herein, unlike advertising, these digital interventions are designed to influence prescribing for particular patients, based on information within the patients' confidential digital medical records, and at the point of prescribing or other treatment decisions.

12. Other digital marketing programs used by Defendants conceal that they are promoting sponsored products and, instead, present as clinical decision support tools (for

example, a COPD severity test or alerts that recommend action based on the provider's assessment of a patient's asthma symptoms). Such programs take providers or patients through a series of steps within the EHR that lead to a recommendation resulting in the likely prescribing of Defendant Pharmaceutical Companies' branded prescription drugs.

13. These programs both have the potential to, and are designed to, interfere with, influence and even skew clinical decision making by providers and are designed and expected to increase utilization and costs. They also may result in inappropriate utilization.

14. There is a reason that Defendants utilize these digital interventions: because they work. Healthcare providers subject to digital interventions, including those which appear as advertisements at the point of prescribing and those which recommend a course of treatment within the EMR's workflow and clinical decision support tools, are much more likely to "resolve the clinical alert" by prescribing the recommended product than if they are subject to traditional pharmaceutical advertising or physician detailing alone.

15. Additional features to these programs reveal that these programs are illegal interventions to induce referral of patients, including federally-insured patients, to prescription drugs marketed by the Pharmaceutical Company defendants.

16. Specifically, these digital marketing programs leverage the unique position of influence that electronic health record systems have for clinicians. EHRs are intended to provide clinical decision support to providers whether through alert buttons, order sets, access to published research, or implementation of published clinical guidelines for care within the patient record. Clinicians expect that the EHR is a tool for clinical decision making and do not expect that clinical decision support materials are designed to cause referrals for prescriptions to specific branded products, to the exclusion of competitor products or other treatment modalities, based on patient-specific information and data about the clinicians' prescribing decisions.

17. Financial arrangements that cause EHRs to induce referrals for branded pharmaceutical products corrupt the clinical decision making process and exploit the unique position of influence the EHR has over clinical decision making at the point of prescribing.

18. By offering, soliciting, paying, and receiving illegal remuneration, Defendants cause, and have caused, the referral of federally insured patients to pharmaceutical drugs marketed by Defendant pharmaceutical companies in violation of the Anti-Kickback Statute.

19. Referrals obtained in violation of the Anti-Kickback Statute are false claims within the meaning of the federal False Claims Act and similar state False Claims Acts. These transactions are not covered by any of the Anti-Kickback safe harbors for referral services or otherwise.

20. These financial transactions are also an attempted end run around recent decisions by the Office of Inspector General not to allow for pharmaceutical companies to provide electronic health records systems to health care providers because of the recognized concern that such transactions may induce referrals of patients to the pharmaceutical companies' prescription drug products.

21. Pharmaceutical company payments to EHR companies for inducing referrals at the point of prescribing essentially achieve the same ends for the pharmaceutical companies. By paying the EHR to influence prescribing decisions, these payments allow the EHR company to reduce the cost of the EHR subscription services for health care providers, making it more likely that the HCPs will select the cheaper EHR and be presented with more digital interventions designed to influence prescribing.

22. Enforcement of the AKS to prohibit financial inducements from pharmaceutical companies to EHR systems in a unique position to influence clinical decision making and prescribing is needed to ensure the integrity of clinical decision making within the EHR.

23. Each claim for reimbursement for prescription drug products or vaccines submitted to a government health care program that was induced by illegal promotional activities

as described herein constitutes a false or fraudulent claim for payment, in violation of the FCA and its state-law counterparts.

24. The conduct alleged herein occurred from at least January 2017 and is ongoing.

25. The FCA was originally enacted during the Civil War, and was substantially amended in 1986 and in 2009. Congress enacted these amendments to enhance and modernize the government's tools for recovering losses sustained by frauds against it after finding that federal program fraud was pervasive. The amendments were intended to create incentives for individuals with knowledge of fraud against the government to disclose the information without fear of reprisals or government inaction, and to encourage the private bar to commit resources to prosecuting fraud on the government's behalf.

26. The FCA provides that any person who presents or causes to be presented false or fraudulent claims for payment or approval, or knowingly makes, uses, or causes to be made or used false records and statements to induce the United States to pay or approve false and fraudulent claims, is liable for a civil penalty for each such claim, plus three times the amount of the damages sustained by the federal government.

27. The FCA allows any person having information about false or fraudulent claims to bring an action on behalf of the government, and to share in any recovery. The FCA requires that the complaint be filed under seal for a minimum of 60 days (without service on the defendants during that time) to enable the United States to (a) conduct its own investigation without the defendants' knowledge, and (b) determine whether to join the action.

28. As set forth below, defendants' actions alleged in this Complaint also constitute violations of the California False Claims Act, Cal. Gov't Code § 12650 *et seq.*, Colorado Medicaid False Claims Act, Colo. Rev. Stat. § 25.5-4-303.5 *et seq.*; the Connecticut False Claims Act, Conn. Gen. Stat. § 4-274 *et seq.*; the Delaware False Claims and False Reporting Act, 6 Del. C. § 1201 *et seq.*; the District of Columbia False Claims Law, D.C. Code Ann. § 2-381.01 *et seq.*; the Florida False Claims Act, Fla. Stat. Ann. § 608.081 *et seq.*; the Georgia State

False Medicaid Claims Act, Ga. Code Ann. § 49-4-168 *et seq.*; the Hawaii False Claims Act, Haw. Rev. Stat. § 661-21 *et seq.*; the Illinois False Claims Act, 740 Ill. Comp. Stat. § 175/1 *et seq.*; the Indiana False Claims and Whistleblower Protection Act, Ind. Code § 5-11-5.7 *et seq.*; the Iowa False Claims Act, IA ST §685.1 *et seq.*; the Louisiana Medical Assistance Programs Integrity Law, La. Rev. Stat. § 46:437 *et seq.*; the Maryland False Health Claims Act, Md. HEALTH-GENERAL Code Ann. § 2-601 *et seq.*; the Massachusetts False Claims Law, Mass. Gen. Laws ch. 12 § 5B *et seq.*; the Michigan Medicaid False Claims Act, Mich. Comp. Laws Ann. § 400.601 *et seq.*; the Minnesota False Claims Act, Minn. Stat. Ann. § 15C.01 *et seq.*; the Montana False Claims Act, Mont. Code Ann. § 17-8-403(1)(a); the Nevada False Claims Act, Nev. Rev. Stat. Ann. § 357.040 *et seq.*; the New Jersey False Claims Act, N.J. Stat. § 2A:32C-1 *et seq.*; the New Mexico Medicaid False Claims Act, N.M. Stat. Ann. § 27-14-1 *et seq.*; the New York False Claims Act, N.Y. State Fin. § 187 *et seq.*; the North Carolina False Claims Act, N.C. Gen. Stat. § 1-605 *et seq.*; the Oklahoma Medicaid False Claims Act, 63 Okl. St. § 5053 *et seq.*; the Rhode Island False Claims Act, R.I. Gen. Laws § 9-1.1-1 *et seq.*; the Tennessee Medicaid False Claims Act, Tenn. Code Ann. §§ 71-5-181 *et seq.*; the Texas Medicaid Fraud Prevention Act, Tex. Hum. Res. Code Ann. § 36.001 *et seq.*; the Vermont False Claims Act, Vt. Stat. Ann. tit. 32, § 630 *et seq.*; the Virginia Fraud Against Taxpayers Act, Va. Code Ann. §§ 8.01-216.1 *et seq.*; and the Washington Medicaid False Claims Act, RCW 74.66 *et seq.*

29. Based on these provisions, *qui tam* plaintiff-relator Barbara Bay seeks to recover all available damages, civil penalties, and other relief for federal and state violations alleged herein, in every jurisdiction to which Defendants' misconduct has extended.

II. PARTIES

A. Plaintiffs

30. *Qui tam* plaintiff-relator Barbara Bay has over ten years of experience working as a digital marketing strategist and health information technology subject matter expert for digital marketing campaigns. She has worked on the design and implementation of campaigns for a

number of large pharmaceutical companies including GSK, Pfizer, Bayer and Sanofi and the digital marketing company, Publicis.

31. The governmental plaintiffs in this lawsuit are the United States and the States of California, Colorado, Connecticut, Delaware, Florida, Georgia, Hawaii, Illinois, Indiana, Iowa, Louisiana, Maryland, Massachusetts, Michigan, Minnesota, Montana, Nevada, New Jersey, New Mexico, New York, North Carolina, Oklahoma, Rhode Island, Tennessee, Texas, Vermont, Virginia, Washington, the District of Columbia, and Doe States 1–20 (collectively "the States").

32. The United States, acting through HHS and its component, the Centers for Medicare & Medicaid Services ("CMS") administers the Medicare program, Title XVIIII of the Social Security Act, 42 U.S.C. § 1395 et seq. ("Medicare"), and grants to states for Medical Assistance Programs ("Medicaid") pursuant to Title XIX of the Social Security Act, 42 U.S.C. § 1396. The federal government funds additional healthcare programs, such as CHAMPUS/TRICARE, CHAMPVA, the Federal Employees Health Benefit Program, and federal workers' compensation programs. To the extent those programs are covered by the federal False Claims Act, those programs are referred to in this Complaint as "federal health care programs."

33. Plaintiffs Doe States 1–20 consist of the States that subsequent to the filing of this Complaint enact false claims act statutes that permit *qui tam* lawsuits, or whose previously enacted statutes become effective after the filing of this Complaint.

34. The States provide health care benefits to certain individuals, based either on the person's financial need, employment status or other factors. One of those programs, Medicaid, is a public assistance program providing for payment of medical expenses for low-income patients. Funding for Medicaid is shared between the federal government and state governments. The Medicaid program subsidizes the purchase of more prescription drugs than any other program in the United States. To the extent those programs are covered by that State's False Claims Act, those programs are referred to in this Complaint as "State health care programs."

B. Defendants

35. Defendant Clinovations, a product line of The Advisory Board ("Clinovations"), is headquartered in Washington, D.C. Clinovations is a consulting firm offering strategic, clinical, and health IT advisory and management services to the government and stakeholders in the public sector, provider, interoperability, and technology domains.

36. Defendant OptimizeRx Corporation ("OptimizeRx") is headquartered in Rochester, Michigan. OptimizeRx is a publicly-traded digital health company "providing healthcare communications solutions for life sciences to engage in streamlined, outcomes-focused dialogue with healthcare providers and patients." Its services connect healthcare providers and patients on a digital platform and provides software solutions and applications for "financial messaging," "brand and therapeutic support messaging," "brand support," and "patient engagement." OptimizeRx partners with pharmaceutical and other life science companies and provides "communication solutions" between life science companies with providers and patients.

37. Defendant PDR, LLC, d/b/a ConnectiveRx ("ConnectiveRx") is headquartered in Whippany, New Jersey, and is owned by private equity firm Genstar Capital. ConnectiveRx was formed in 2015 from the merger of three companies: PKSW ("pioneers in affordability), LDM ("innovators in adherence"), and the Physician's Desk Reference (PDR). In 2017, ConnectiveRx expanded to partner with CareForm, a "leader in technology-enabled specialty medication hub services" and acquired The Maculuso Group, "experts in paperless and technologically advanced patient support and reimbursement services." It is a digital communications company which uses technology based support for biopharmaceutical manufacturers to provide strategic solutions to promote prescribing and adherence to prescription drugs. Among other services, Defendant ConnectiveRx represents that it has extensive networks with EHRs and pharmacies that can be used to enable "multichannel digital and traditional communication solutions" for pharmaceutical brands to deliver messages to physicians and patients at the point of prescribing and dispensing.

38. Defendant Point of Care Partners is headquartered in Hollywood, Florida. Point of Care Partners is a management consulting firm assisting healthcare organizations in the evaluation, development and implementation of health information management strategies in the electronic world.

39. Defendant Change Healthcare Inc. f/k/a Change Healthcare Solutions, LLC ("Change Healthcare") describes itself as a "leading independent healthcare technology company, focused on accelerating the transformation of the healthcare system through insight and innovation." Change Healthcare is headquartered in Nashville, Tennessee and publicly-traded on the Nasdaq stock exchange. Change Healthcare Solutions, LLC was purchased by Emdeon in 2015, at which time the company was rebranded to Change Healthcare. In 2016, Change Healthcare Holdings, Inc. and McKesson Corporation announced the creation of Change Healthcare Inc., which combined substantially all of Change Healthcare Holding Inc.'s business with the majority of McKesson's information technology unit. McKesson owns approximately 70% of the new company, with the remaining equity stake held by Change Healthcare stockholders. In January 2021, UnitedHealth Group's OptumInsight agreed to acquire Change Healthcare. In a December 2021 filing with the SEC, Change Healthcare announced that the deal would not be finalized until at least April 2022.

40. Defendant GlaxoSmithKline ("GSK") is a global pharmaceutical company. Defendant GlaxoSmithKline, LLC, a Delaware limited liability company, is the United States subsidiary of GlaxoSmithKline plc. GlaxoSmithKline, LLC is the successor of SmithKline Beecham Corporation. GlaxoSmithKline, LLC has headquarters in Research Triangle Park, North Carolina and in Philadelphia, Pennsylvania. GSK has a broad portfolio of pharmaceutical products with a focus on respiratory disease, HIV, immuno-inflammation and oncology. GSK is also one of the largest vaccine companies in the world.

41. Defendant Pfizer Inc. ("Pfizer") is a global pharmaceutical company incorporated in Delaware and headquartered in New York, New York. Pfizer has a broad portfolio of

pharmaceutical products including vaccines and drugs for internal medicine, rare diseases, inflammation and immunology, and oncology.

42. Defendant AllScripts Healthcare Solutions ("AllScripts") is a publicly traded company providing health information technology solutions including electronic health records, population health, patient engagement and revenue cycle management services. Founded in 1986, AllScripts is incorporated in Delaware and has principal executive offices in Chicago, Illinois. AllScripts' EHR solutions include Sunrise, Paragon, AllScripts Touchworks EHR, AllScripts Professional EHR, Practice Fusion, and BOSSNet.

43. Defendant EPIC Systems Corporation ("EPIC") is a privately-held electronic health record company headquartered in Verona, Wisconsin. More than 250 million persons have records in an EPIC system. Like most EHRs, EPIC claims that it has embedded decision support tools to support clinical practice and yield better outcomes.

44. Doe Defendants 1-100 are pharmaceutical companies, EHR companies, and EHR/health IT consultants or aggregators who have engaged in conduct of the type described herein but whose identities are currently unknown to Relator.

III. JURISDICTION AND VENUE

45. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. § 1331 and 31 U.S.C. § 3732(a), which specifically confers jurisdiction on this Court for actions brought under 31 U.S.C. § 3730.

46. This Court has supplemental jurisdiction, pursuant to 28 U.S.C. § 1367, over Relator's state law claims, as those claims and Relators' federal law claims are sufficiently related to form part of the same case or controversy under Article III of the United States Constitution. This Court has express supplemental jurisdiction over the States' claims pursuant to 31 U.S.C. § 3732(b), as the States' claims arise from the same transactions and occurrences as the federal action.

47. This Court has personal jurisdiction over defendants, pursuant to 31 U.S.C. § 3732(a), as defendants can be found in, reside in, and/or transact business in this judicial district.

48. Venue is proper, pursuant to 31 U.S.C. § 3732(a) and 28 U.S.C. §§ 1391(b)–(c), as defendants can be found in, reside in, and/or transact business in this judicial district. In addition, statutory violations, as alleged herein, occurred in this judicial district.

IV. STATUTORY AND REGULATORY BACKGROUND

A. The False Claims Act

49. The FCA imposes civil liability on any person who, inter alia, (1) knowingly presents or causes to be presented, a false or fraudulent claim for payment or approval; or (2) knowingly makes, uses or causes to be made or used a false record or statement material to a false or fraudulent claim. 31 U.S.C. §§ 3729(a)(1)(A)-(B).

50. The FCA defines a "claim" to include "any request or demand, whether under a contract or otherwise, for money or property and whether or not the United States has title to the money or property that – (1) is presented to an officer, employee or agent of the United States; or (2) is made to a contractor, grantee, or other recipient, if the money or property is to be spent or used on the Government's behalf or to advance a Government program or interest." *Id.* § 3729(b)(2).

51. The FCA defines the term "knowing" and "knowingly" to mean "that a person with respect to information – (i) has actual knowledge of the information; (ii) acts in deliberate ignorance of the truth or falsity of the information; or (iii) acts in reckless disregard of the truth or falsity of the information." *Id.* § 3729(b)(1)(A). The FCA does not require proof of specific intent to defraud. *Id.* § 3729(b)(1)(B).

52. The FCA provides that the term "material" means "having a natural tendency to influence or be capable of influencing the payment or receipt of money or property." *Id.* § 3729(b)(4).

53. Any person who violates the FCA is liable for a mandatory civil penalty for each such claim, plus three times the damages sustained by the Government. *Id.* § 3729(a)(1).

B. The Anti-Kickback Statute

54. The federal health care Anti-Kickback statute, 42 U.S.C. § 1320a-7b(b), arose out of Congressional concern that payoffs to those who can influence health care decisions will result in the provision of goods and services that are medically unnecessary, of poor quality, or even harmful to a vulnerable patient population. To protect the integrity of federal health care programs from these difficult to detect harms, Congress enacted a prohibition against the payment of kickbacks in any form, regardless of whether the particular kickback actually gives rise to overutilization or poor quality of care.

55. The Anti-Kickback statute ("AKS") prohibits any person or entity from making or accepting payment to induce or reward any person for referring, recommending or arranging for the purchase of any item for which payment may be furnished under a federally-funded health care program. 42 U.S.C. § 1320a-7b(b). Under this statute, drug companies may not offer or pay any remuneration, in cash or kind, directly or indirectly, to induce the ordering or recommending of drugs that may be paid for by Medicare, Medicaid, CHAMPUS/TRICARE, CHAMPVA, and other federal health care programs.

56. The Anti-Kickback Statute criminalizes the soliciting or receiving of money in return for the referral of an individual to an item paid for by Medicare or other federal program funds. *See United States ex rel. Gohil v. Sanofi U.S. Services Inc.* 500 F.Supp.3d 345 (E.D. PA 2020) (citing 42 U.S.C. § 1320a–7b(b)).

57. Section 1320a–7b(b), entitled "Illegal remunerations," has two subsections. Section 1320a–7b(b)(1) provides:

> whoever knowingly and willfully *solicits or receives* any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind—

> (A) in return for referring an individual to a person for the furnishing or arranging for the furnishing of any item or service for which payment may be made in whole or in part under a Federal health care program, or
> (B) in return for purchasing, leasing, ordering, or arranging for or recommending purchasing, leasing, or ordering any good, facility, service, or item for which payment may be made in whole or in part under a Federal health care program, shall be guilty of a felony and upon conviction thereof, shall be fined not more than $25,000 or imprisoned for not more than five years, or both. *Id.* § 1320a–7b(b)(1) (emphasis added).

58. Section 1320a-7(b)(2) criminalizes the offering or paying of money in return for referral of an individual to an item paid for by federal program funds:

> whoever knowingly and willfully *offers or pays* any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind to any person to induce such person—
> (A) to refer an individual to a person for the furnishing or arranging for the furnishing of any item or service for which payment may be made in whole or in part under a Federal health care program, or
> (B) to purchase, lease, order, or arrange for or recommend purchasing, leasing, or ordering any good, facility, service, or item for which payment may be made in whole or in part under a Federal health care program, shall be guilty of a felony and upon conviction thereof, shall be fined not more than $25,000 or imprisoned for not more than five years, or both. *Id.* § 1320a–7b(b)(2) (emphasis added).

59. The law not only prohibits outright bribes to physicians and other health care providers, but also prohibits payments to any person in a position to induce referrals or arrange for the writing of prescriptions for a pharmaceutical company's prescription drugs.

60. Concern about improper drug marketing practices prompted the Inspector General of the Department of Health and Human Services to issue a Special Fraud Alert in 1994 concerning prescription drug marketing practices that violated the Anti-Kickback law. Special Fraud Alert: Prescription Drug Marketing Schemes, 59 Fed. Reg. 65,376 (Dec. 19, 1994).

61. The OIG warned that the AKS is implicated by programs that offer "cash or other benefits to pharmacists (or others in a position to recommend prescription drug products) in exchange for performing marketing tasks in the course of pharmacy practice related to Medicare or Medicaid. The marketing tasks may include sales-oriented 'educational' or 'counseling' contacts, or physician and/or patient outreach, etc." *Id.* Programs raising AKS concerns include financial incentives to pharmacists for promoting selection of a specific product. "The

pharmacies were induced to help persuade physicians, who were unaware of the pharmacies' financial interest, to change prescriptions." OIG further noted that "[a] marketing program that is illegal under the anti-kickback statute may pose a danger to patients because the payment may interfere with a physician's judgment in determining the most appropriate treatment for a patient" and may also increase costs.

62. The 1994 Fraud Alert specified the following factors to evaluate whether a payment is improper

- Payment is made to a person in a position to generate business for the paying party
- Payment is related to the volume of business generated
- Payment is more than nominal in value and/ or exceeds fair market value of any legitimate service or is unrelated to any service at all other than referral of patients.

63. Similarly, the 2003 OIG Guidance for Pharmaceutical Manufacturers addressed concerns about kickbacks and illegal remuneration in marketing pharmaceutical products. The first step in evaluating arrangements or practices that present a significant potential for abuse involves identifying any remunerative relationship between the pharmaceutical manufacturer or its representatives and persons or entities in a position to generate federal health care business. The next step is to identify whether any one purpose of the remuneration is to induce or reward the referral or recommendation of business payable in whole or in part by a federal program. "A lawful purpose will not legitimize an unlawful purpose."

64. Several potential aggravating circumstances that can be useful in identifying arrangements presenting the greatest risk include:

- Does the arrangement or practice have the potential to interfere with or skew clinical decision-making? Does it have the potential to undermine the clinical integrity of a formulary process? If the practice provides information, is the information complete, accurate and not misleading?

- Does the arrangement or practice have the potential to increase costs to federal programs or beneficiaries?
- Does the arrangement or practice have the potential to increase the risk of overutilization or inappropriate utilization?
- Does the arrangement or practice raise patient safety or quality of care concerns?

65. The key question to assess is whether the individual/entity receiving remuneration is in a position to influence the referral, ordering, or prescribing of the manufacturer's products, even if the person or entity may not itself purchase those products. *See* OIG Compliance Program Guidance for *Pharmaceutical* Manufacturers, 68 Fed. Reg. 23,731 (May 5, 2003) ("2003 OIG Guidance").

66. Claims that derive from referrals that are tainted by kickbacks are not eligible for reimbursement and are materially false or fraudulent claims. Knowing submitting or causing the submission of such a claim for reimbursement is a violation of the federal False Claims Act, 31 U.S.C. § 3729, and the analogous state statutes.

V. BACKGROUND

67. In 2009, the United States enacted the Health Information Technology and Clinical Health ("HITECH") Act to authorize the Office of the National Coordinator for Health Information Technology ("ONC") to establish the functionality that EHR products must meet in order for new technologies to be considered certified. Under the HITECH Act, ONC established a certification program for EHR technology. As part of the certification program, EHR vendors attest to ONC-authorized certification bodies (ACBs) and accredited testing laboratories that their software meets the certification requirements established by ONC.

68. Under the HITECH Act, the U.S. Department of Health and Human Services ("HHS") established the Medicare and Medicaid EHR Incentive Programs (also known as the "Meaningful Use program"), which provided incentive payments to healthcare providers who demonstrated "meaningful use" of certified EHR technology. In 2015, Congress replaced the

Meaningful Use program with the Merit-based Incentive Payment System ("MIPS"), pursuant to the Medicare Access and CHIP Reauthorization Act of 2015 ("MACRA"). The HITECH Act identified the "meaningful use" of interoperable health records throughout the United States as a critical national policy goal.

69. To obtain certification, EHR vendors must attest to an ACB that their EHR product satisfies the applicable certification criteria, submit to certification testing by an accredited testing laboratory, and pass such testing. After obtaining certification, an EHR vendor must maintain that certification by complying with all applicable conditions and requirements of the certification program including accurately, reliably and safely performing its certified capabilities.

70. Two key requirements for certification of an EHR are implicated by this action.

71. First, each certified EHR must demonstrate that it has a workflow that provides Clinical Decision Support ("CDS") tools to ensure quality care and to guard against risk of error in medical decision-making.

72. Under federal law, it is expected that clinical decision support will "occur when a user is interacting with technology" and will present the provider/ user with "evidence-based decision support interventions" triggered off of patient characteristics including problem lists, medication lists, allergies and intolerances, demographics, lab tests, and vital signs. *See* 45 C.F.R § 170.315(a)(9) (2015). Such interventions should be based on clinical research/ guidelines that can be cited. Further, information regarding the clinical research/guideline supporting the intervention, the funding source, the developer and the release date of the intervention must be available. *Id. See also* https://www.federalregister.gov/documents/2012/09/04/2012-20982/health-information-technology-standards-implementation-specifications-and-certification-criteria-for#p-651.

73. ONC has described "clinical decision support" thusly: "CDS provides clinicians, staff, patients and other individuals with knowledge and person-specific information,

intelligently filtered or presented at appropriate times, to enhance health and health care. CDS encompasses a variety of tools to enhance decision making in the clinical workflow. These tools include computerized alerts and reminders to care providers and patients; clinical guidelines; condition-specific order sets; focused patient data reports and summaries; documentation templates; diagnostic support; and contextually relevant reference information, among other tools."

74. The National Academy of Medicine has described appropriate CDS as requiring computable biomedical information, person-specific data, and a reasoning or inferencing mechanism that combines knowledge and data to generate and present helpful information to clinicians, patients, and care team members as care is being delivered. CDS, in the right context, can reduce errors, improve quality of care, reduce cost and ease the cognitive burden on health care providers. *See* National Academy of Medicine, "Optimizing Strategies for Clinical Decision Support," (2017).

75. The Centers for Disease Control identifies "clinical decision support systems" as computer-based programs that analyze data within EHRs to provide prompts and reminders to assist health care providers in implementing evidence-based clinical guidelines at the point of care. For example, for cardiovascular disease prevention, the EHR might flag cases of hypertension or hyperlipidemia, provide information on treatment protocols, prompt questions on medication adherence, and provide recommendations for health behavior changes. CDS guidelines note that "[l]egal considerations for [Clinical Decision Support Systems] begin with the vendors who interpret and transmit guidelines into algorithms . . . Vendors must fully disclose the sources used to build the knowledge base for their software[.]" https://www.cdc.gov/dhdsp/pubs/guides/best-practices/index.htm; *see also* Gorman, et al., *Clinical Decision Support Systems for the Practice of Evidence-Based Medicine*, Journal of the American Medical Informatics Association, Volume 8, Issue 6, pages 527-534 (2001).

76. Second, each certified EHR must include the capacity to order prescription medication by electronic means (also known as e-prescribe).

77. The reasonable expectation of health care providers is that EHRs will provide clinical recommendations for patient care within the workflow and patient record. Providers are very familiar with clinical decision alerts and other pop-up content that is supposed to provide helpful clinical guidance for patient care.

78. The pharmaceutical industry has a keen interest in marketing its pharmaceutical products to physicians and, traditionally, has done so through sales calls, distribution of FDA-approved marketing materials, medical conferences and continuing medical education programs, and advertising in both mainstream and specialized publications of various kinds.

79. It is well established that there is a high risk of fraud and abuse in certain marketing practices implemented over the years by the pharmaceutical industry.

80. OIG has issued guidance documents addressing interactions between pharmaceutical manufacturers and those in a position to refer patients for their products. *See OIG Compliance Program Guidance for Pharmaceutical Manufacturers*, 68 Fed. Reg. 23,731 (May 5, 2003) ("2003 OIG Guidance"); Inspector Gen., Dep't of Health & Hum. Servs., *Special Fraud Alert: Prescription Drug Marketing Schemes* (1994), *reprinted in* HHS-OIG Special Fraud Alerts, 59 Fed. Reg. 65,372 (Dec. 19, 1994) ("1994 Special Fraud Alert"). Though these guidance documents are not binding, several courts have treated them as persuasive when evaluating whether specific schemes violate the AKS. *See, e.g.*, *United States ex rel. Suarez v. AbbVie, Inc.*, No. 15 C 8928, 2019 WL 4749967, at *6 (N.D. Ill. Sept. 30, 2019); *United States ex rel. Forney v. Medtronic, Inc.*, No. 15-6264, 2017 WL 2653568, at *4 & n.2 (E.D. Pa. June 19, 2017).

81. The 2003 OIG Guidance anticipates that there are significant concerns about kickbacks and illegal remuneration when pharmaceutical companies market their products. As OIG notes, the federal AKS places constraints on common business activities involving sales,

marketing, discounting and purchaser relations. The statute reaches not only offer or payment of anything of value in exchange for ordering an item or service, but also offer or payment for arranging for or recommending the purchase or ordering of any item or service. The statute extends equally to solicitation and acceptance of remuneration for referrals.

82. The 1994 Fraud Alert specified the following factors to evaluate whether a payment is improper: (1) payment is made to a person in a position to generate business for the paying party; (2) payment is related to the volume of business generated; and (3) payment is more than nominal in value and/ or exceeds the fair market value of any legitimate service or is unrelated to any service at all other than referral of patients.

83. In addition, OIG has forbidden pharmaceutical and other life science companies from providing EHRs directly to providers and has taken the position that such conduct would violate the AKS and that there is no cognizable policy reason for creating an exception to this prohibition. https://www.federalregister.gov/documents/2020/12/02/2020-26072/medicare-and-state-health-care-programs-fraud-and-abuse-revisions-to-safe-harbors-under-the.

84. Pharmaceutical companies are aware that remuneration to obtain referrals, as defined by the Anti-Kickback Statute, is prohibited, and that these prohibitions are at issue in digital marketing programs.

85. Pharmaceutical companies, including GSK, have created internal business rules that disavow that payments for digital marketing interventions are intended to induce referrals to branded drugs or that they may be used to influence prescribing decisions. GSK's business rules, for example, state explicitly: "interventions are not intended to influence the prescribing of specific medications for a specific patient" and cannot include content that could be "deemed to influence prescribing decisions for specific medication for a specific patient." GSK rules further provide that "digital CDS interventions may only occur outside the actual product eRX event and must always be unbranded." These rules recognize that such influencing of prescribing decisions would violate the AKS or at least provide a high risk of same.

86. Nonetheless, the digital interventions at issue in this action have the potential to place the commercial interest of the sponsoring company ahead of the need for unbiased, evidence-based information for health care providers and clinical needs of patients. Such sponsored content, within the EHR, is not providing neutral medical guidance but is intended to, and does, have the potential to influence, and even skew, clinical decision-making based on the commercial interests of the branded prescription medication manufacturer. Many of these interventions guide the provider toward choosing a desired branded pharmaceutical product at the critical period when the provider is reviewing the patient's individual medical record and making the decision to prescribe.

87. Some of the programs use financial messaging, a particularly effective tool, and provide coupons and other messages geared to pricing discounts within the EHR. Whether or not the coupons are used, or limited to commercial pay patients only, financial messages at the point of prescribing are very effective at inducing prescribers to choose the branded product more often than if the digital intervention was not present. The offer of a discount or coupon gives the provider something that appears to be of value to give their patients and perhaps even an opportunity for the provider to grow their patient base in return for prescribing the promoted drug. In fact, the payments are precisely to cause the change in prescribing behavior that are then measured by the EHR aggregator.

88. Significantly, many of these digital intervention arrangements allow pharmaceutical companies to obtain a guarantee from the EHR that they will have exclusive access to the providers within the EHR and to exclude competitor companies and drugs from similar interventions. This guarantee of "100% SOV" and a "right of first refusal" is a condition of payment for many digital intervention programs even when other clinical options, including competitor medications and treatments, might improve outcomes for the patient.

89. Equally problematic is that some of these interventions, including the ones marketed by Clinovations, similar to the one designed for Purdue in Practice Fusion, mask

pharma sponsorship through seemingly-neutral clinical tools, tests or measures that purport to be based on non-commercial standards while actually being designed to lead the patient or provider to fill or prescribe the branded product.

90. Also problematic are the comprehensive interventions offered by Point of Care Partners to train sales representatives to insert content directly into the workflow of top EHRs so that new drugs and vaccines can be added to the EHR at launch by the pharma sales force and lists of patients eligible for the medications and vaccines generated by the pharma sales force within the EHR. These EHR toolkits provide value to the health care provider and introduce direct pharma intervention into the workflows of certified EHRs to obtain increased prescribing. In this way, the pharma company may directly insert itself into clinical care through working with providers to create patient lists based on EHR data, inserting ordering of medications in order sets, and arranging for proactive recruitment of patients for drug adherence.

91. EHRs, and industry aggregators and advisors, have been successful in marketing the digital "real estate" within the EHR as available for exclusive contracts with pharmaceutical manufacturers to influence physicians at the point of clinical decision making and prescribing.

92. Industry statistics note that by 2015, 87% of office-based physicians were using an EHR and 85% of them were e-prescribing by 2017. By 2017, there were over 370 EHRs and/or e-prescribe platforms in use by providers.

93. Since the mid-2010s, several firms have sought to bridge the relationship between the pharmaceutical companies and other life sciences companies and the large number of EHR companies. These consultants and so-called industry "aggregators" – including Defendants OptimizeRx and ConnectiveRx and Clinovations (now owned by The Advisory Board) – negotiate arrangements between branded pharmaceutical companies and EHR companies to promote branded pharmaceuticals through digital interventions within the EHR.

94. Financial arrangements are made between the branded pharmaceutical company and the aggregator/consultant and, in turn, between the aggregator/consultant and EHRs. The

EHR companies provide exclusive access for digital marketing programs within the EHR, with a focus on influencing e-prescribing decisions, and data to the pharmaceutical company clients, through the aggregator, in order to allow the aggregator/consultant and pharmaceutical company to assess the return on their investment by analyzing increases in the volume and value of prescriptions resulting from their sponsored interventions.

95. The EHR companies may also provide data to the pharmaceutical companies that may be useful in assessing future marketing strategies with HCPs and patients.

96. Internal documents reveal that all participants in the transactions -- the pharmaceutical companies, the electronic health record companies, and the digital marketing aggregators – understand that the primary purpose of these payment is to cause the EHRs to implement interventions that will induce prescribing of specific branded drugs for the patients of targeted providers with specific clinical and demographic characteristics. The pharmaceutical companies require detailed data and proof of the effectiveness of the intervention in affecting prescribing habits and would not be content to know that the content serves solely as an "educational" or "awareness campaign" about disease treatment. Participants in the transactions track the increase in prescriptions associated with each digital intervention and consider that evidence in reassessing the next contract or statement of work.

97. It is within that context of assessing return on investment, and changes in provider prescribing habits before and after the intervention's introduction, that the parties negotiate payments for each intervention. These payments can be considerable and typically range from several hundred thousand to a million dollars per program and, thereby, can provide a steady stream of revenue for EHR companies.

98. In fact, a number of EHR companies anticipate that a primary source of revenue for them may not be sales of the EHR to health care providers but, instead, sale of information to pharmaceutical and other health sciences companies about provider prescribing habits and access to those providers to order to influence their clinical decisions.

VI. ALLEGATIONS

A. Defendants Have Knowingly Paid and Received Unlawful Remuneration in Exchange for the Prescription of Drug Products and Vaccines

99. Defendants have knowingly exchanged, and continue to exchange, remuneration for digital marketing programs within EHRs that constitute unlawful remuneration under the Anti-Kickback Statute, exclude competitor drugs from similar interventions, and have the potential to skew clinical decision making.

1. Defendants Recognize that Digital Interventions Must Be Consistent with AKS

100. Defendants have developed business rules for digital marketing that explicitly recognize that the Anti-Kickback Statute forbids the payment of remuneration to influence the referral of federal program beneficiaries unless that remuneration falls within defined safe harbors.

101. Defendants include additional references to the need to comply with the Anti-Kickback Statute within contracts and statements of work, as well as public filings and public presentations.

102. Defendants recognize that their payments for digital interventions in EHRs do not fall within any of the AKS safe harbors.

2. Defendants' Digital Interventions Are Designed and Intended to Influence Providers to Increase Prescriptions of Sponsored Drugs and Vaccines

103. The following are examples of digital intervention programs implemented in EHRs in violation of the Anti-Kickback Statute and which result in the knowing presentation of false or fraudulent claims to Medicare, Medicaid and other federal and state programs.

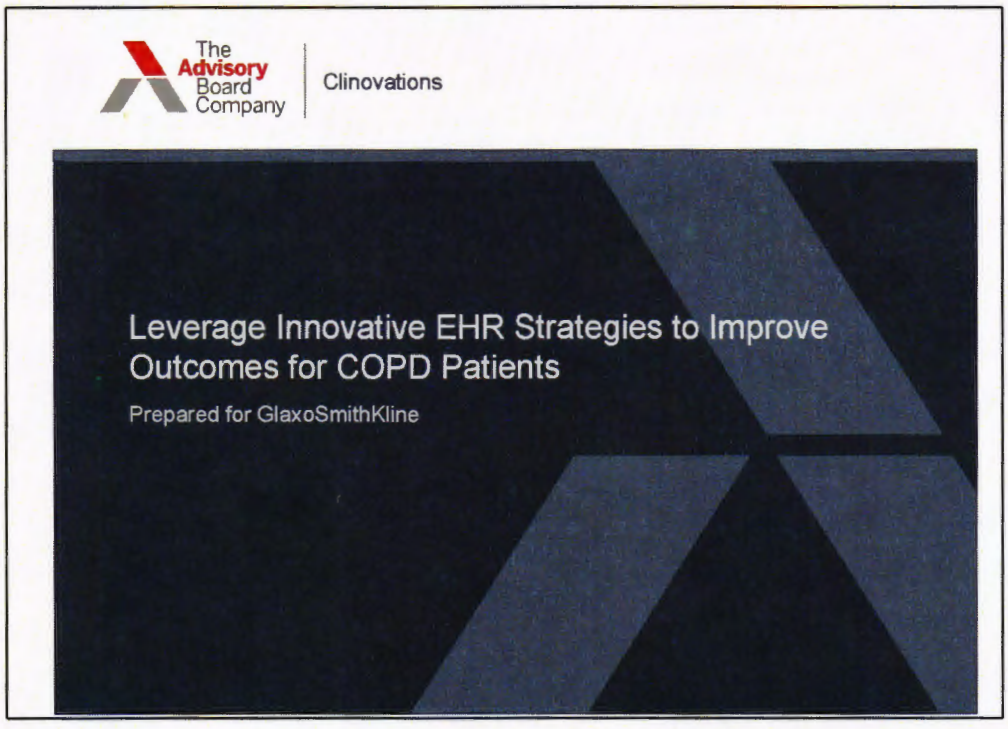
i. Clinovations, a product line of The Advisory Board

104. Clinovations presents itself as "a consulting firm offering strategic, clinical and health IT advisory and management services to the government and stakeholders in the public sector, provider, interoperability and technology domains."

105. Since 2015, Clinovations has been owned by The Advisory Board, headquartered in Washington, DC.

106. In December 2017, Clinovations presented a proposal to GSK's respiratory marketing team to create CDS tools within EHR workflows to assess patients with COPD. Although Relator left GSK before the COPD Assessment Test was integrated in workflow for any large integrated delivery networks as envisioned by Clinovations, it is her understanding that GSK's Brian Keebhler, Channel Lead for the Respiratory Franchise, intended to move forward with implementation of the Clinovations proposal for use of a digital intervention tool to assess COPD and to build a GSK team to work on the intervention.

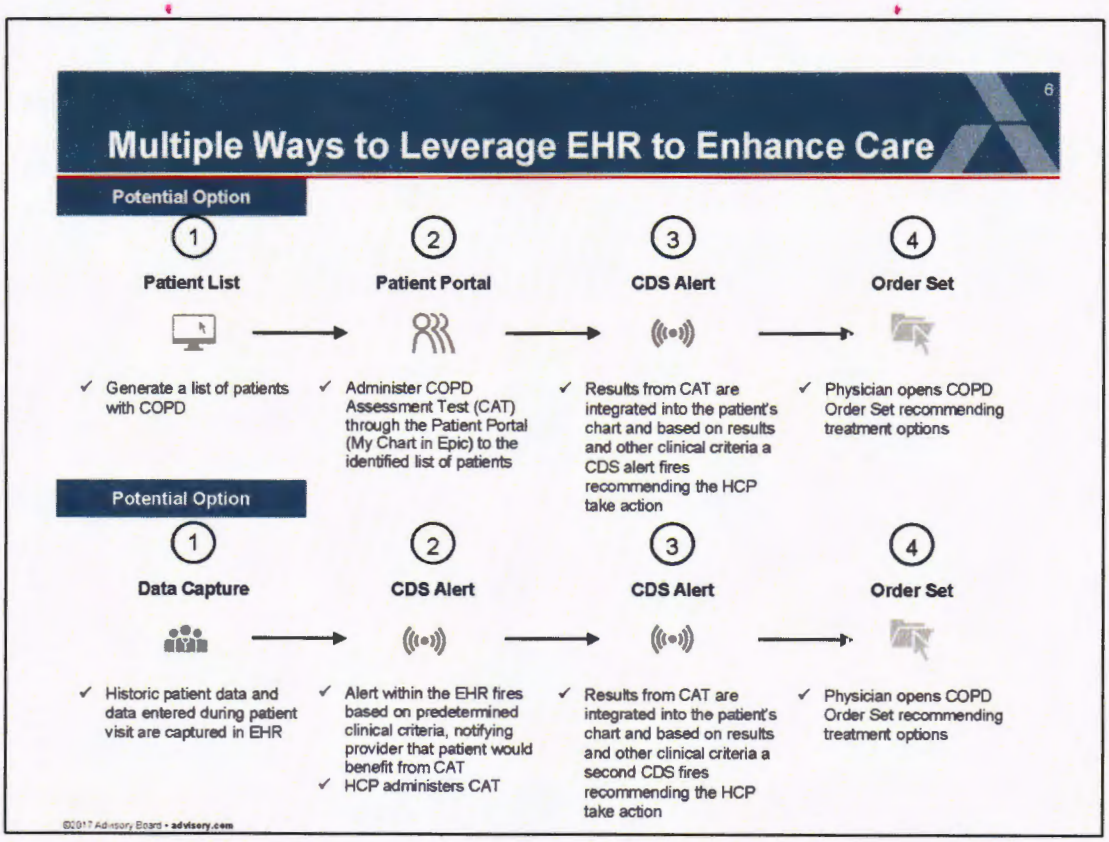
107. Clinovations' proposal to GSK was based on workflow interventions it had already completed within EPIC for other pharma companies. In 2017, Clinovations promoted that it could "Leverage Innovative EHR strategies to Improve Outcomes for COPD Patients."



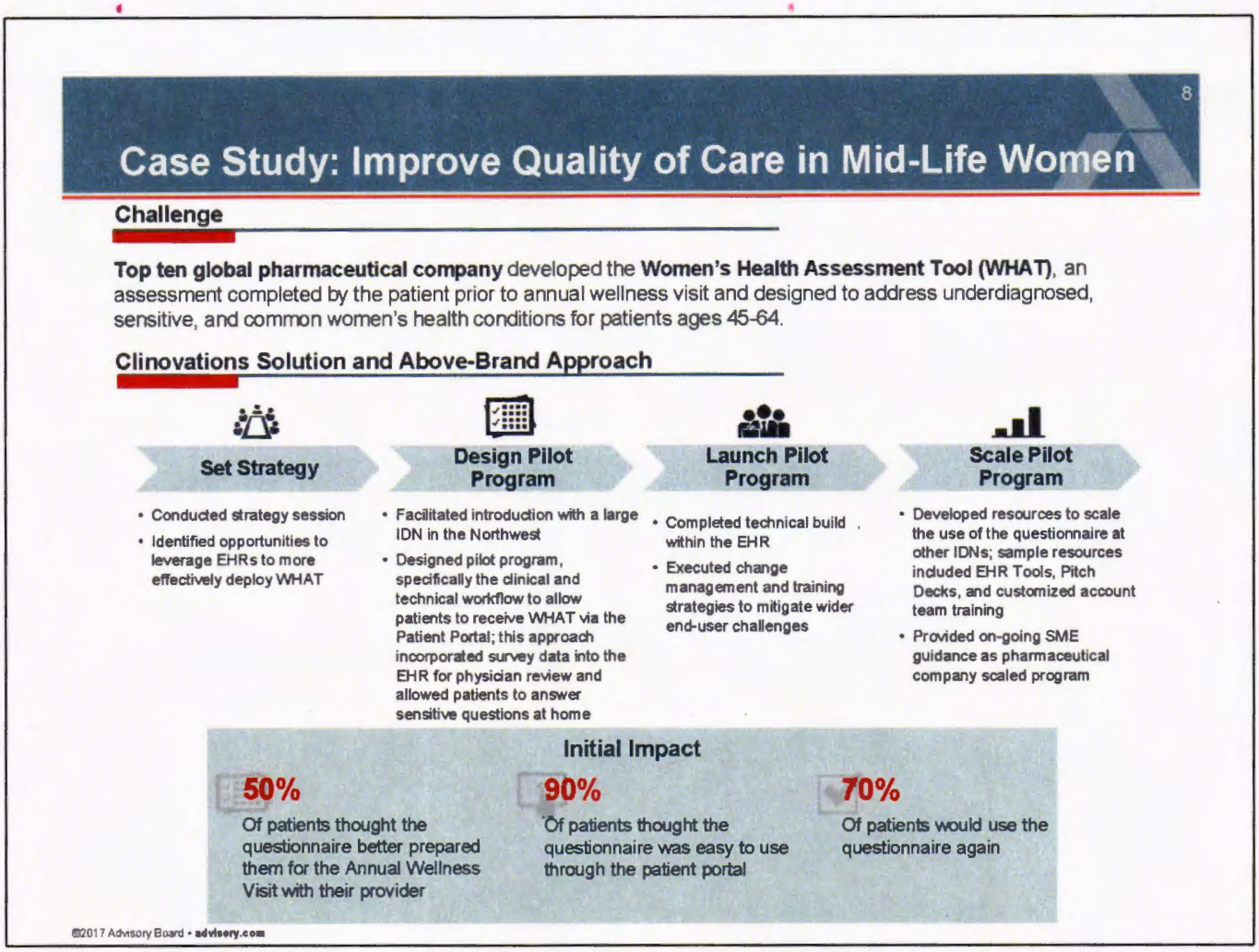
108. The proposal was to embed a COPD assessment test into the EHR systems and patient portals of large integrated delivery networks ("IDNs") (including large hospital systems

and affiliated providers). Clinovations anticipated starting the effort within the Epic EHR program which is utilized by most large IDNs. Clinovations would then receive data from the IDN and measure the impact that the intervention had on patient outcomes. Clinovations promised that part of its contract would be to create "Build Guides," identify priority IDNs, and develop a pitch deck for the IDNs to "overcome objections if they already had clinical protocols and pathways for COPD assessment."

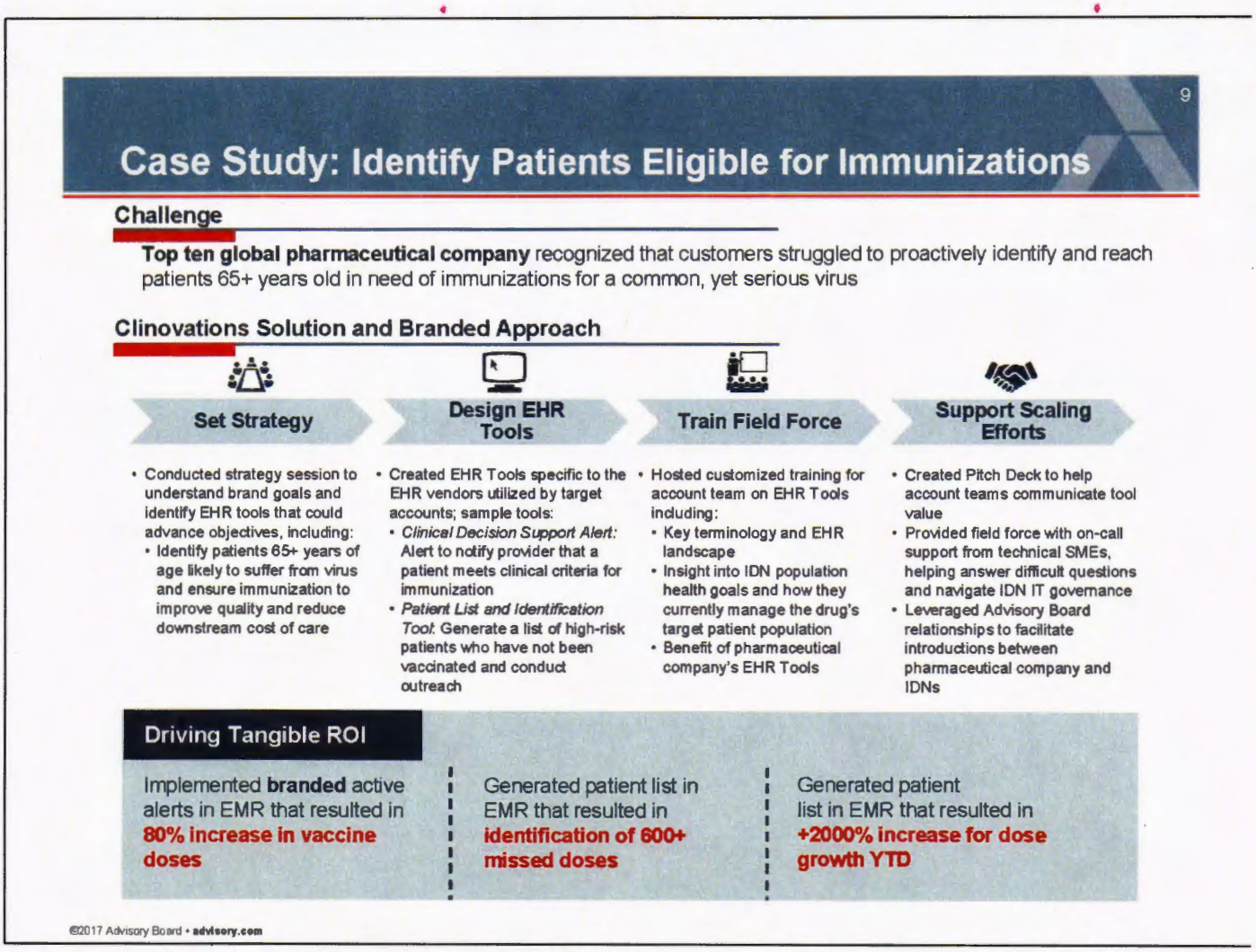
109. Clinovations presented that it could work with both Cerner and EPIC functionality to implement digital interventions to prompt application of the COPD assessment test. For example, Clinovations presented as one option that it could generate a list of patients with COPD, administer the COPD Assessment Test to these patients through the patient portal, and integrate the results of the test into the patient's chart. Based on the results from the assessment test and other clinical criteria, a CDS alert would fire, recommending the provider "take action." The provider would then open a COPD order set recommending treatment options. Alternatively, or in addition, a CDS alert might fire during a patient encounter based on data within the patient's chart, prompting the provider to administer the COPD assessment test. The results from the test would then be integrated into the patient's chart, and, based on the results and other clinical criteria, a second CDS would fire recommending the provider "take action." Again, the provider would open a COPD order set which would recommend treatment options.



110. Clinovations provided two case studies of similar work it had already done on behalf of other clients. For example, Clinovations described how it had assisted a "[t]op ten global pharmaceutical company" in leveraging EHRs to deploy a "Women's Health Assessment Tool" ("WHAT") the pharmaceutical company had developed. Clinovations worked with the pharmaceutical company to introduce the WHAT into the EHR for a "large IDN in the Northwest." The WHAT was incorporated into the IDN's clinical and technical workflow such that it was presented to patients through the patient portal prior to their annual wellness visits. According to Clinovations, the WHAT was designed to address "underdiagnosed, sensitive and common women's health conditions." Ms. Bay surmises this intervention was implemented on behalf of pharmaceutical company Bayer.



111. Similarly, Clinovations described how it had assisted a "[t]op ten pharmaceutical company" leverage EHR tools to "identify and reach patients 65+ in need of immunizations for a common, yet serious virus." Clinovations described how it created a CDS alert and patient list and identification tool to promote vaccination for these patients. Ms. Bay surmises the pharma company was likely Merck. Clinovations noted the success of its programs in "facilitating introductions between pharma and IDNs" resulting in 80% increase in vaccine doses and 2000% increase for dose growth.



112. Through this program, Clinovations allowed GSK and other pharmaceutical manufacturers to be directly involved in the design, development, and content of clinical tools that should be evidence-based and free of commercial influence.

ii. ConnectiveRx

113. ConnectiveRx presents itself as a leading provider of technology-enabled biopharmaceutical services. Its majority investor is Genstar Capital, a private equity firm focused on investments in financial, healthcare, industrial and software sectors.

114. ConnectiveRx has a number of biopharmaceutical clients and develops targeted marketing programs to help "power the medication journey," "inform and activate prescribers to

grow the market and the brand" and "inform and motivate patients to start and remain on therapy." They offer "adherence solutions to start, maintain and restart lapsed patients." In 2017, ConnectiveRx claimed to reach more than 200 million patients through their network of EMRs representing more than 300,000 providers (over 50% of active e-prescribers). They claimed involvement in over 2 billion prescriptions annually.

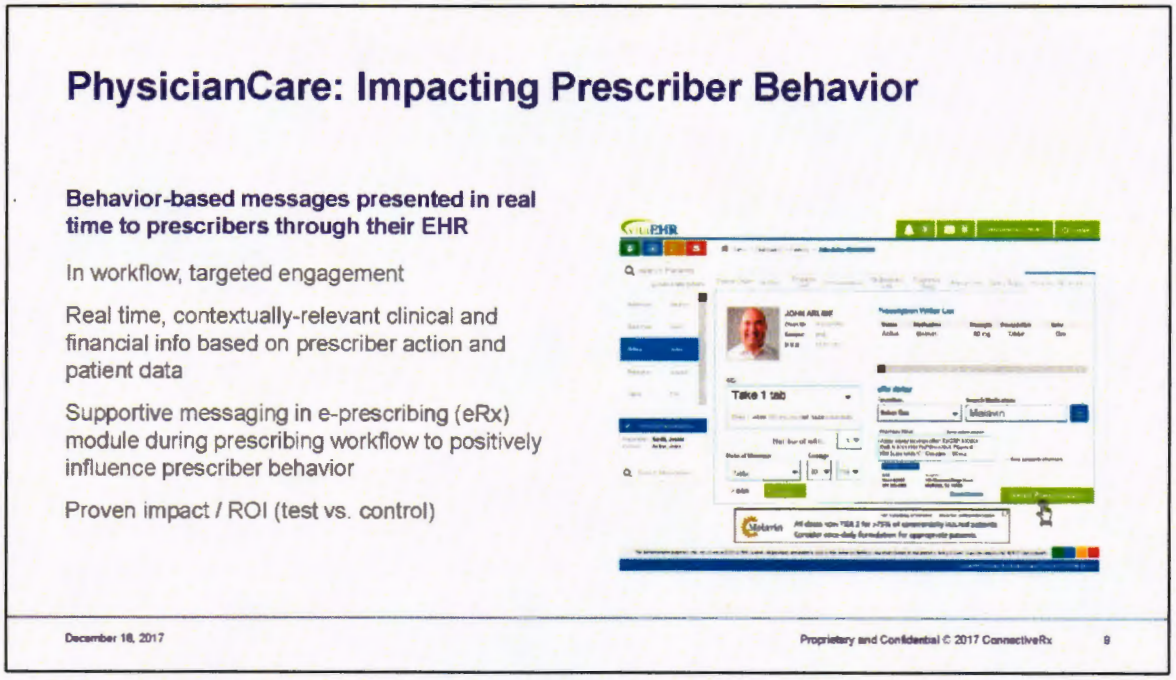
115. ConnectiveRx has relationships with many of the larger EHRs including Epic, Cerner, Meditech, and AllScripts as well as smaller EHRs like MicroMDs and eMDs. ConnectiveRx programs use both financial and clinical messages to induce prescribing of their clients' branded medications. By 2021, ConnectiveRx claimed that it reached 68% of all prescribers including 50,000 in EPIC/Cerner hospital platforms and 80,000 in AllScripts hospital and ambulatory care platforms.

116. ConnectiveRx's programs include "In-Workflow, Point of Care EMR Programs" and "Pharmacy-Based Programs." ConnectiveRx's EMR programs are known as "PhysicianCare" (designed to "impact[] prescriber behavior") and "ScriptGuide" (designed to "motivat[e] patient adherence"). ConnectiveRx's pharmacy-based program is known as "CarePoints" and is designed to "driv[e] patient awareness and adherence." All of these programs are designed to increase the writing and filling of prescriptions for sponsored drugs.

117. In 2017 and 2018, GSK contracted with ConnectiveRx to use its "PhysicianCare" Program to market drugs in its respiratory franchise, including Advair (asthma), BREO (COPD), Anoro (COPD), Flovent HFA (asthma), Arnuity Elipta (asthma) and Nucala (severe asthma), and to market its Meningitis B and shingles vaccines, Bexsero and Shingrix.

118. The "PhysicianCare" program works generally as follows: GSK provides ConnectiveRx with a list of its target prescribers and those prescribers are presented with "clinical or financial info based on prescriber action and patient data" when working in their EHR. In other words, promotional materials (of various sorts, as discussed below), are presented to prescribers in real-time based on the clinical information in their patients' charts or based on

their actions (such as prescribing a competing product). For example, for Shingrix, GSK paid for digital alerts to be presented within the EHR whenever the provider selected any medication intended for patients over 50 years old or if the provider selected the competitor Merck vaccine, Zostavax. ConnectiveRx describes this as "[s]upportive messaging … during prescribing workflow to positively influence prescriber behavior" and notes that there is "[p]roven impact / ROI[.]"



PhysicianCare: Impacting Prescriber Behavior

Triggering criteria may include:

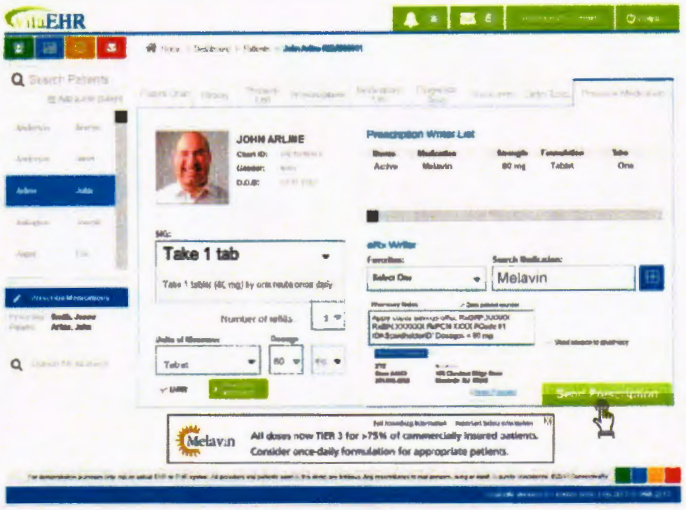
Upon Entry/Login (Non-Patient Specific)

Within e-Prescribing Tool:

- Patient Details: Age, Gender
- Patient History:
  - Medication (eRx) History
  - Vaccination History (MVX/CVX code) – including absence of vaccination

Within Immunization Module: Based on presence/absence of MVX/CVX code

Option to include full PI and ISI



GSK PhysicianCare: Newly Approved, Unique Strategies

	New & Unique Ways GSK is Impacting Prescriber Behavior
Arnuity Ellipta & Flovent	• First to leverage formulary messaging • First to tailor formulary based on state coverage percentage • First to promote competitive coverage advantage in targeted states
Bexsero	• First to utilize MVX/CVX data fields to trigger message • First to utilize message placement within immunization module • Leveraged patient-age as trigger point within eRx to promote immunization
Nucala	• First to trigger using patient history of 'market basket' products • First unbranded specialty product to raise disease awareness
Shingrix	• First to trigger upon eRx selection of competitor (Zostavax)

119. In its project service agreements, ConnectiveRx regularly warranted that all of the HCPs who would be receiving promotional messages under its programs had consented to use of their patients' medical data within the EHR to search and generate promotional digital interventions.[1] ConnectiveRx also warranted that it would not "pass through" funds paid by GSK to providers through rebate or discount. ConnectiveRx further agreed not to disclose publicly or utilize in any promotional or marketing materials the existence of the agreement or ConnectiveRx's relationship with GSK. Importantly, ConnectiveRx warranted that "its activities on behalf of GSK" were not and would not be in conflict "with any other contractual obligations" ConnectiveRx had or would subsequently undertake. The parties expressly warranted that they intended to implement the Agreement without violation of AKS and other laws and guidance over pharma relationships with providers.

120. In similar fashion, in 2021, Pfizer engaged ConnectiveRx to drive utilization of its vaccines, Prevnar and Trumenba.

121. In all of these programs, the pharma companies contract for exclusive access to the digital interventions created by ConnectiveRx. For example, it was standard in GSK's Project Service Agreements with ConnectiveRx to specify that the agreement was exclusive and that ConnectiveRx had not and would not enter into any contract in conflict with the one that it had executed with GSK. Therefore, when GSK contracted with ConnectiveRx to market Shingrix within the clinical workflow of an EHR or pharmacy network, it paid to block its Merck competitor from a similar message within the EHRs of ConnectiveRx's EHR and pharmacy network partners. The same would be true for branded pharma or generic competition.

122. Some of ConnectiveRx's other programs direct messages directly to patients based on their prescribing and fill history either in the provider's office or at the pharmacy. These are known as the "ScriptGuide" and "CarePoints" programs. Through the CarePoints

[1]Notably, no mention is made of patient consent to such usage.

program, pharmaceutical companies pay for digital alerts to be presented within a pharmacy's electronic work flow. These alerts are triggered based on patient transactions including whether the patient is filling and/or refilling certain specified branded prescriptions. Patients receive a personalized "CarePoints" message (that appears to be from the pharmacy) at the point a prescription is filled. The payments from the pharma company, through ConnectiveRx, to the pharmacy networks also include promotional messages for pharmacists in the form of education and encouragement to promote medication adherence, or, in the case of vaccines, initiation and completion of a vaccine series.

123. Pfizer implemented one such program to "Reach Patients at Point of Care" for its Meningitis B vaccine Trumenba.[2] A ConnectiveRx PowerPoint describes the program as intended to "[d]riv[e] awareness of Trumenba first or second dose to 16-23Y patient." Moreover, it notes that the program is "[t]urnkey to enable high utilization" and that "ROI" on the program will be "[q]uantifiable."

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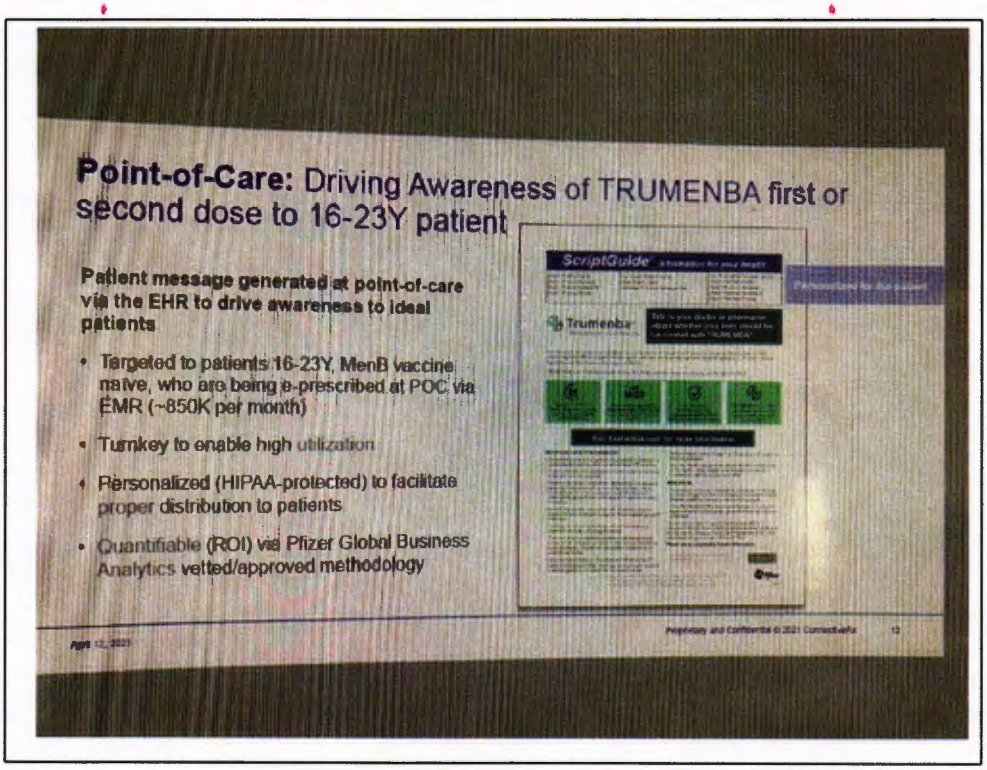
2 Trumenba is a vaccine for Meningococcal Group B disease (MenB). The CDC recommends a MenB vaccine series for healthy adolescents and young adults age 16-23. Immunocompromised individuals and certain others may have reduced immune response and there are contraindications to use.



124. Patients were targeted in two ways – through their pharmacists and through their prescribers. Under the former, when a 16-23 year old patient filled a prescription in a pharmacy partnering with ConnectiveRx, the prescription would trigger a "personalized message for the patient[.]" The patient would then receive their prescription and a promotional document regarding the Trumenba vaccine. Under the latter, when an eligible patient visited his/her health care provider, he/she would receive similar promotional material regarding the Trumenba vaccine following their visit. For both programs, ConnectiveRx provided Pfizer with feedback about the resulting increase in utilization.

125. A Pfizer/ ConnectiveRx contract in 2020/2021 similarly sought to drive utilization of Prevnar 13 vaccines[3] specifically among patients with rheumatoid arthritis. Through the sponsored program, individual RA patients were similarly targeted with messages from their

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3 Prevnar is a vaccine for pneumococcal disease recommended by the CDC for children and certain adults. Immunocompromised individuals and certain others may have reduced immune response and there are contraindications to use.

prescribers and their pharmacists about the Prevnar 13 vaccine. The messages were designed to "[m]otivate[] prescribed RA patients to [] talk to their pharmacist about Prevnar 13[.]" ConnectiveRx reported to Pfizer that these messages generated an incremental increase in Prevnar vaccination and accelerated vaccination rates by 9% among RA patients. Pfizer is believed to have paid $1 million for this program.

126. Previous to that, in 2017/2018, Pfizer contracted with Change Healthcare to pilot a similar CDS Pharmacy messaging program for Trumenba. These programs directed messages at pharmacists any time they administered a flu, MCV4, or HPV vaccine to a patients aged 16-23. The message would direct the pharmacist: "Patient may be a candidate for Trumenba vaccine. Discuss vaccination options with patient." In 2021, Change Healthcare, then doing business as Relay Health, a division of McKesson, presented similar initiatives to Pfizer for the same services.

127. GSK relied on ConnectiveRx's "Physician Care" program to promote several of its pharmaceutical products. For example, ConnectiveRx designed a "Physician Care" program for GSK to promote Nucala, a medication approved for severe asthma in patients with a specific phenotype (eosinophilic) to be used, when appropriate, in combination with other asthma medications.[4]

128. The intervention operated in the following manner.

- GSK provided ConnectiveRx with a list of "target HCPs." When a target HCP logged into his/her EHR system, a branded or unbranded message would appear on screen. An unbranded promotional message would say something like, "Did you know eosinophils play a role in severe asthma?" ConnectiveRx promoted these services to GSK by noting

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4 Nucala is a medication approved for severe asthma in patients with a specific phenotype (eosinophilic) to be used, when appropriate, in combination with other asthma medications. In 2017, its indication was expanded somewhat to include patients with eosinophilic asthma and a rare autoimmune condition called polyangitis. To Relator's understanding, Nucala would not generally be a first line treatment for asthma, even severe asthma.

that "PhysicianCare messages" like this "can generate awareness and encourage appropriate treatment of severe asthma." As the target HCP continued through the EHR – including at his/her login screen and at patient chart selection – branded or unbranded promotional messages for Nucala would continue to appear.

- Branded or unbranded Nucala messages would continue to appear once the physician was in a patient chart, and, in particular, when the physician opened the e-prescribing tool to order a prescription for the patient. When the physician accessed the prescribing module and searched for a medication, if the physician selected a "target medication" for prescription, the Nucala messaging would appear. Notably, Nucala messages were triggered based on patient age and history of other therapies or medications (complementary or competitive). There was no requirement that the message trigger based on genetic testing. For example, according to "targeting details" presented in October 2017, a Nucala message would appear in the e-prescribe tool if a patient was 18 or older, had a history of receiving decadron, deltasone, methylprednisone, or prednisone (all glucocorticoid steroids) in the prior 90 days and the provider was attempting to e-prescribe Advair (Diskus) 500/50, Advair (HFA) 230/21, Dulera 200/5, Breo (200/25), or Symbicort (160/4.5) (all asthma medications).
- The Nucala messaging would remain on the screen the entire time the physician completed the e-prescription.

129. ConnectiveRx made the Nucala messaging available throughout its entire EHR network.

130. ConnectiveRx reported to GSK on the effectiveness of the intervention by reporting on claims during the program period "to determine incremental increase attributed to the program."

131. ConnectiveRx developed a similar program for Juluca,[5] a prescription medication used without other antiretrovirals to treat HIV when a provider determines that certain conditions are met. In an October 2017 presentation to GSK, ConnectiveRx presented its "recommendation" to use the PhysicianCare program to "accelerate prescribed volume" and to use the "ScriptGuide" and "CarePoints" programs to ensure these prescriptions were filled, i.e., "to drive fill."

132. The PhysicianCare intervention operated in the following manner. GSK provided ConnectiveRx with a list of "target HCPs." When a "target HCP" logged into the EMR system, he/she would receive a Juluca message. In addition, when a target HCP was in the e-prescribe tool, if he/she selected Juluca or an adjunctive or competitive therapy, a Juluca message would again appear.

133. The ScriptGuide intervention operated in the following manner. When a prescriber ordered Juluca, the EHR system would automatically cause personalized promotional materials to be provided to the patient. Personalization could include the patient's prescriber, PHI, and pharmacy information. In addition, these materials could include "passive financial offers with clear instructions and patient benefits." GSK also utilized the CarePoints program to "drive fill" of Juluca.

134. Like all of ConnectiveRx's programs, success of these programs was assessed through the increase in the writing and filling of prescriptions of the sponsored product.

135. GSK paid in excess of $400,000 to promote Juluca in EHRs and pharmacy networks that partnered with ConnectiveRx.

136. ConnectiveRx developed similar programs for GSK's Arnuity and Flovent, prescription medications for control and prevention of asthma. GSK utilized ConnectiveRx's "PhysicianCare" program to induce prescriptions of Arnuity and Flovent and Connective Rx's

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5 Juluca is a product of ViiV Healthcare, a joint venture between Pfizer and GSK to develop therapies for HIV infection.

"ScriptGuide" program to induce prescriptions of Flovent. The goal of these programs was to "drive consideration and prescription of Arnuity Ellipta while maintaining Flovent's long-standing legacy position among core prescribers." The intervention was designed to target prescribers based on their historical prescribing habits. GSK, working with online content management and marketing firm Red Ventures, divided HCPs into four different groups based on their prescribing habits: those who were writing prescriptions for Arnuity but not Flovent; those who were writing prescriptions for Flovent but not Arnuity; those who were writing prescriptions for both; and those who were writing prescriptions for neither.

137. Promotional messages about Arnuity and Flovent delivered to targeted HCPs included material about the drugs' formulary status. For instance, banner ads delivered in multiple states stated: "Over [XX]% of commercial patient lives in your state have favorable coverage for [Arnuity/Flovent]." Another branded message for Arnuity stated: "Discover 24-hour efficacy with ONE inhalation daily."

138. The ScriptGuide program for Arnuity also included a "patient savings message" such as: "Eligible commercially insured patients pay no more than $10."

139. ConnectiveRx developed a similar program for GSK's Triumeq, a prescription medication used to treat HIV-1 infection. ConnectiveRx presented its "recommendations" for "driving Triumeq volume" to GSK in December 2017. ConnectiveRx recommended utilizing the PhysicianCare program to "accelerate and maintain prescribed volume" and the ScriptGuide and CarePoints programs to ensure those prescriptions were filled.

140. Through the PhysicianCare program, Triumeq promotional messages were delivered to target HCPs when they logged into their EMRs and when they prescribed Triumeq or adjunctive or competitive medications. Through the ScriptGuide program, promotional materials were also provided to the patient automatically as a result of the HCP prescribing Triumeq. GSK also utilized the CarePoints program to promote Triumeq. These programs were intended to "drive fill."

141. As always, ConnectiveRx reported to GSK on the success of the interventions based on the resulting increase in prescriptions.

142. For all of its programs, ConnectiveRx promises to provide an ROI analysis using de-identified data from its network of "eRX/EMR/EHR partners." This ROI analysis is based on the increase in the number of prescriptions filled as shown in fill data recorded by the pharmacy and shared with ConnectiveRx for analysis and reporting to the pharmaceutical sponsor.

143. The deliverable from ConnectiveRx is the final measurement of the impact of the intervention on prescribing. Payment was not based on disease education alone but on inducing increased scripts.

144. ConnectiveRx has implemented digital interventions of the type described above for GSK, Pfizer, and other pharmaceutical manufacturers, and may have implemented additional programs. These programs share similar characteristics of digital intervention at the point of prescribing or point of prescription fill based on patient characteristics. In addition, these contracts are for exclusive "share of voice," such that competitor products are excluded from similar digital interventions. Finally, the deliverable for these programs is a calculable ROI associated with the intervention determined by increase in prescriptions filled as compared to prior to introduction of the program.

145. Many of these programs generate prescriptions paid for by federal and state health programs including Medicare, Medicaid and other programs.

iii. Point of Care Partners

146. Point of Care Partners ("POCP") is a management consulting firm, headquartered in Hollywood, Florida. It describes its role as "assisting healthcare organizations in the evaluation, development, and implementation of health information management strategies in the electronic world." Among other things, POCP assists life science companies with programs to "leverage EHR technology to achieve your goals" and "add powerful EHR tools to your strategy."

147. POCP's products include "customized EHR guides" for over 25 EHRs, including Athena, Cerner, EMDs, GE Centricity, Practice Fusion, AllScripts, eClinical Works, EPIC, and NextGen. POCP markets these EHR guides as a tool that can be used by the pharma sales force to "accelerate your strategy and objectives in the EHR clinical workflow." More specifically, the guides provide the "specific EHR information needed so health systems and large group practices make the EHR changes needed to identify and treat more patients with your brand." POCP also sells "EHR Build Kits" for "more complicated EHR programs that leverage advanced EHR capabilities for innovative clinical programs." In addition to providing information about EHR-specific language for pharma to match with its brand strategy, POCP solicits business by creating materials that are "customized to each brand to support attaining brand sales objectives."

148. POCP uses explicit language making clear that its commercial business is building solutions into the EHR clinical workflow to allow "physicians to use the EHR to identify patients for your brand." They also build "Custom Health IT Education for Marketing and Field Teams" that can "provide key insights to drive sales leveraged on EHR capabilities."

149. POCP creates "Internal EHR Reference Guides," "EHR Best Practice Guides," and EHR Toolkits for each promoted medication or vaccine including for GSK's Shingrix and ViiV's Juluca.

150. The purpose of all of these programs is to drive promotion of the GSK product within the EHR workflow and to train GSK sales force on how to work with health care providers to identify and recruit patients for specific medications and vaccines. The EHR Toolkits allow GSK's sales force to work with a provider's staff to add medications or vaccines into the EHR workflow; and to create patient lists, alerts, and other clinical decision support tools, all with the intention of promoting GSK's products.

iv. OptimizeRx

151. OptimizeRx is a "digital health company that is focused on bringing life sciences support to patients and providers." The company has had exponential growth due to agreements

with top pharmaceutical manufacturers and health information technology partnerships. The company reports an average ROI of 8:1 for its digital interventions, described more fully below, with some interventions having an ROI as high as 20:1.

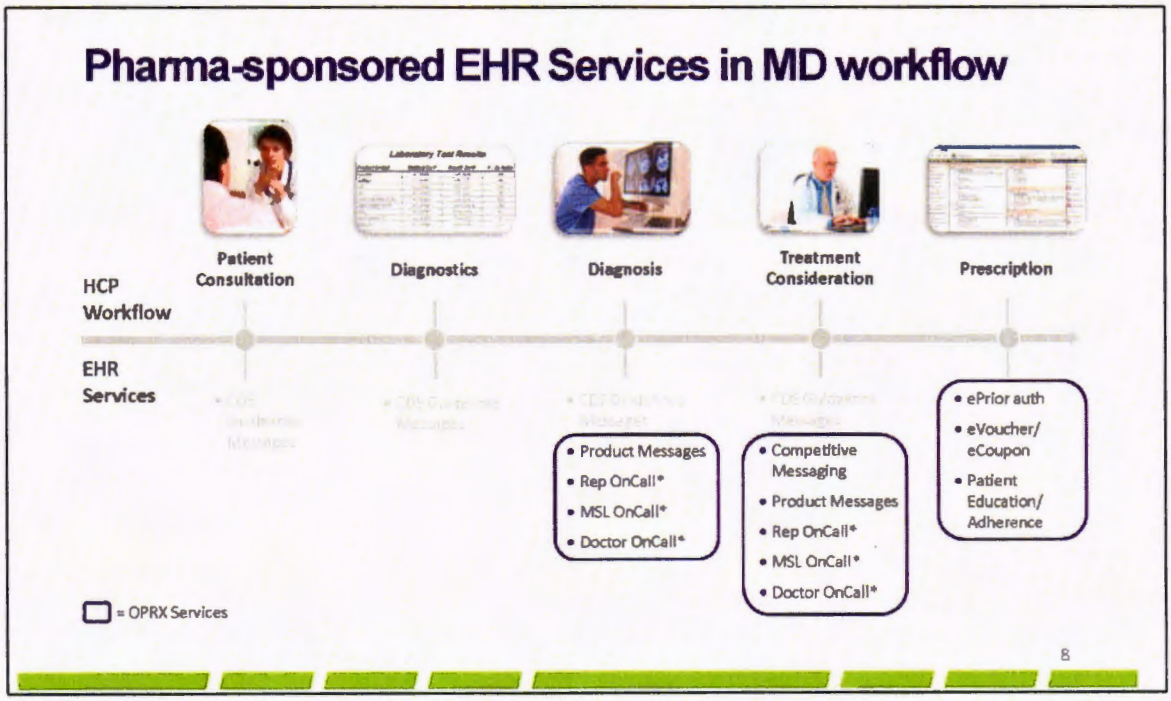
152. OptimizeRx advertises that its programs are intended to deliver information from "life science partners" to providers and patients. For example, they advertise that they provide brand messaging from the moment a provider signs into his/her EHR and that they target providers based on NPI, specialty, and other analytics. Further, "while providers are actively planning or delivering care, information about your treatment is delivered inline within the patient chart while they are entering notes, reviewing labs, entering diagnoses and searching for treatment."

153. At the point of prescription or "confirmation of treatment" as OptimizeRx calls it, the workflow is programmed to deliver prescribing information and coupon or co-pay cards "that a patient can walk away with – on their mobile device or in print." OptimizeRx offers to pharma that "your financial assistance program can even be displayed alongside the real-time benefit check." At discharge, pharma financial assistance and patient support programs are inserted into the discharge paperwork.

154. One presentation provided by OptimizeRx to GSK in August 2017 is illustrative of what is provided to pharmaceutical clients. Titled "GSK & OptimizeRx" the 2017 presentation asks "*Why does Pharma Need to Move Their Resources into the EHR"* and then explains, what is fairly understood by now, that "EHRs are the digital platform where providers live" and that sales reps have declining real world access to providers. OptimizeRx identifies as a "Key challenge" that the "EHR landscape is fragmented" and represents that OptimizeRx is "the leading aggregator in the EHR market" providing the essential link between the pharma brand and, at that time, over 370 EHRs and 500K HCPs.

155. The PowerPoint describes the services it can provide to branded pharma in terms of clinical message interventions at each stage of the EHR workflow, from patient consultation,

diagnostics, diagnosis, treatment considerations, and prescription. Depending on the phase within the workflow, the pharma brand can purchase a range of intervention options from simple product messages to services including "Rep On Call," "MSL On Call," or "Doctor On Call." At the time of treatment consideration, offerings also include "Competitive Messaging" and "Product Messages."



156. In addition, OptimizeRx emphasizes that it has developed a "Financial Messaging Network" that will provide "Outstanding ROI" for the brand and demonstrates through graphics that financial messages are the "most effective digital promotional tactic." Patient savings cards and eVouchers are integrated into the EHR workflow and even into the patient portal.

EHR Financial Assistance

Overview

- *Ability to influence Physician at Point of Prescribe*
  - *Visibility of patient financial support is key influencer on physician decision to complete eRx*
- *Opportunity to embed financial message in provider's e-prescribe workflow, deliver offer electronicallyto pharmacy, and make print version of financial offer available to provider to give to patient*
- Can target financial message by physician Specialty, patient age, demographics, and other criteria
- OptimizeRx network reaches over 500,000 prescribers via 370 EHR partners

Metrics

- *ROI on financial messaging programs average 520%,*

higher than any other digital tactic measured

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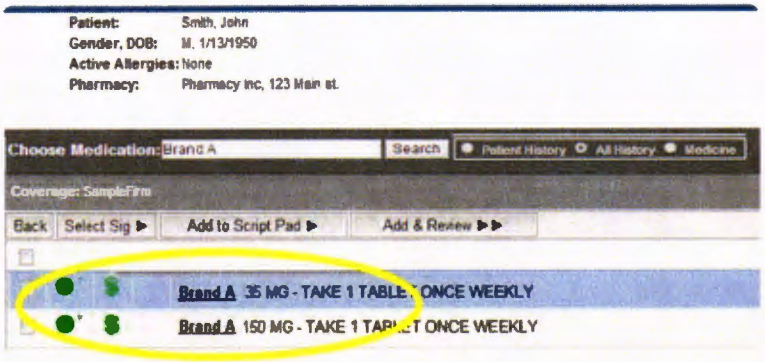
Workflow Overview

Step 1: Search

Health Care Provider Searches for a Brand Within EHR and is Alerted of Potential Savings Availability for Patient

Step 2: Selection

Step 3: Print or Text



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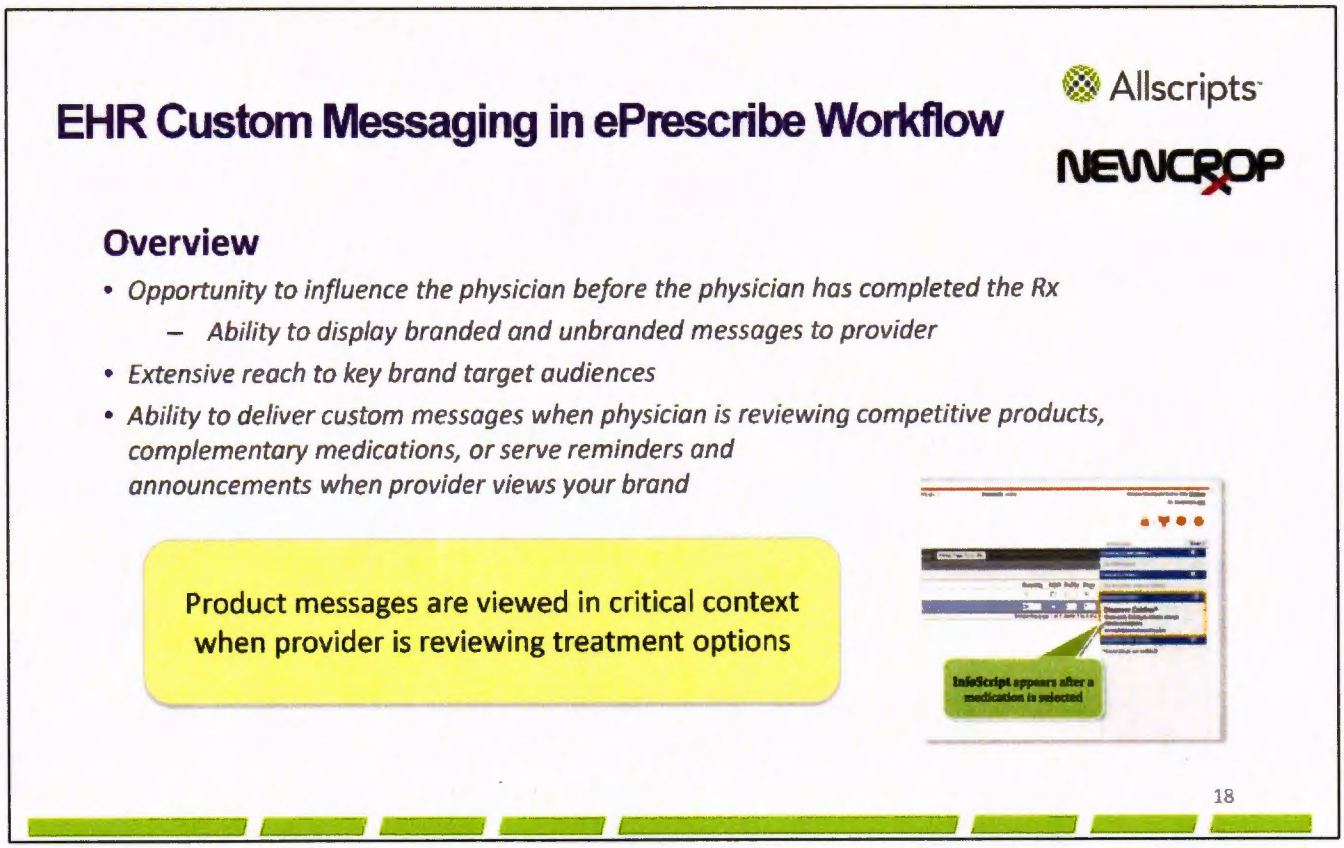
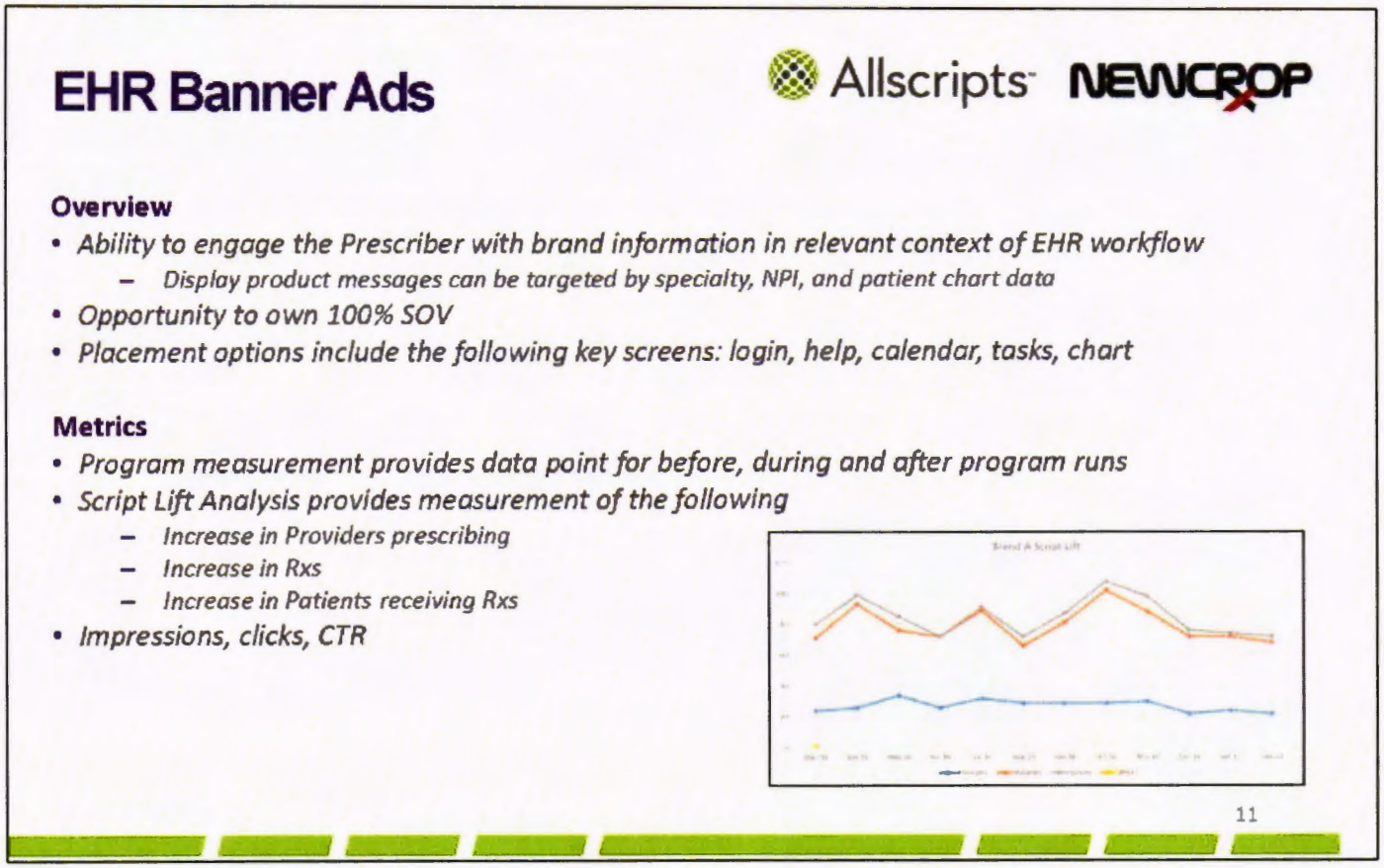
157. OptimizeRx was only able to place its banner ads in AllScripts and NewCrop EHRs. (This is part of why GSK worked with multiple EHR aggregators and consultants.) With these ads, OptimizeRx emphasized that its programs allowed its brand customers to "influence the physician before the physician has completed the Rx" and that it provided the "ability to deliver custom messages when physician is reviewing competitive products, complementary medications, or serve reminders and announcements when provider views your brand."



158. The ability to insert promotional material into the EHR workflow, particularly during the provider's assessment, diagnosis, and prescription activity meant that "product messages are viewed in critical context when provider is reviewing treatment options."

159. OptimizeRx also emphasized that its services inserted messages throughout the "EHR workflow," that messaging could be targeted by specialty, NPI, and patient chart data, and that the brand had the "opportunity to own 100% SOV." In other words, the pharmaceutical manufacturer could block all competitors from reaching these providers.



160. Finally, OptimizeRx described the metrics it would use to report on success of the interventions. These included "Script Lift Analysis," which would measure the "increase in providers prescribing," "increase in Rxs," and "increase in patients receiving Rxs."

161. OptimizeRx did a "deep dive" pitch to GSK on its financial messaging program in December 2017, specifically for its asthma/COPD drug Trelegy.

162. In the pitch, OptimizeRx stated that it had been "partnering with pharmaceutical companies on Financial Messaging Programs" for over seven years and that, at the time, it was

working with more than 25 pharmaceutical companies ("including 8 out of top 10 pharma") and over 110 brands.

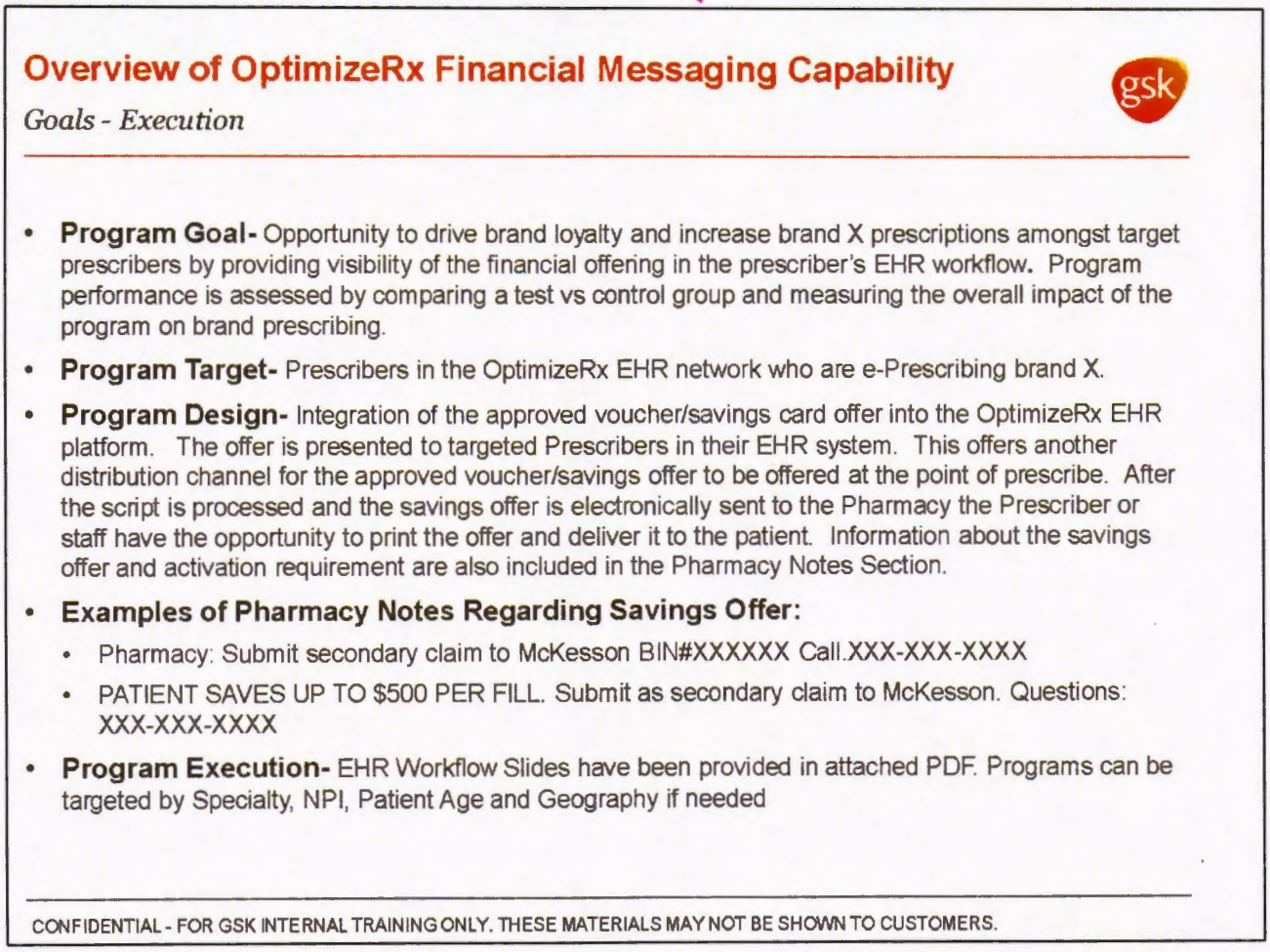
163. OptimizeRx pitched that presenting a financial message about savings for the patient was an "HCP trust building factor" and that research showed that "visibility of savings for patient is important to HCP at point of prescribing."

164. OptimizeRx further promoted its services by noting that its network consisted, at the time, of 370 EHR, EMR, and e-prescribe systems (allowing it to reach more than 500,000 HCPs) and that it had an exclusive partnership with AllScripts with respect to its "financial messaging" capability.

165. OptimizeRx described the financial messaging program as an "[o]pportunity to drive brand loyalty and increase brand X prescriptions amongst target prescribers by providing visibility of the financial offering in the prescriber's EHR workflow."

166. The program operated by "integrating" the voucher/savings card into the OptimizeRx EHR platform such that the offer would be presented to prescribers in their EHR system. In addition, after the script is processed, the savings offer is electronically sent to the pharmacy and the prescriber can print the offer and deliver it to the patient.

167. The success of the program was measured in the "overall impact of the program on brand prescribing."



Overview of OptimizeRx Financial Messaging Capability

Goals - Execution

- **Program Goal-** Opportunity to drive brand loyalty and increase brand X prescriptions amongst target prescribers by providing visibility of the financial offering in the prescriber's EHR workflow. Program performance is assessed by comparing a test vs control group and measuring the overall impact of the program on brand prescribing.
- **Program Target-** Prescribers in the OptimizeRx EHR network who are e-Prescribing brand X.
- **Program Design-** Integration of the approved voucher/savings card offer into the OptimizeRx EHR platform. The offer is presented to targeted Prescribers in their EHR system. This offers another distribution channel for the approved voucher/savings offer to be offered at the point of prescribe. After the script is processed and the savings offer is electronically sent to the Pharmacy the Prescriber or staff have the opportunity to print the offer and deliver it to the patient. Information about the savings offer and activation requirement are also included in the Pharmacy Notes Section.
- **Examples of Pharmacy Notes Regarding Savings Offer:**
  - Pharmacy: Submit secondary claim to McKesson BIN#XXXXXX Call.XXX-XXX-XXXX
  - PATIENT SAVES UP TO $500 PER FILL. Submit as secondary claim to McKesson. Questions: XXX-XXX-XXXX
- **Program Execution-** EHR Workflow Slides have been provided in attached PDF. Programs can be targeted by Specialty, NPI, Patient Age and Geography if needed

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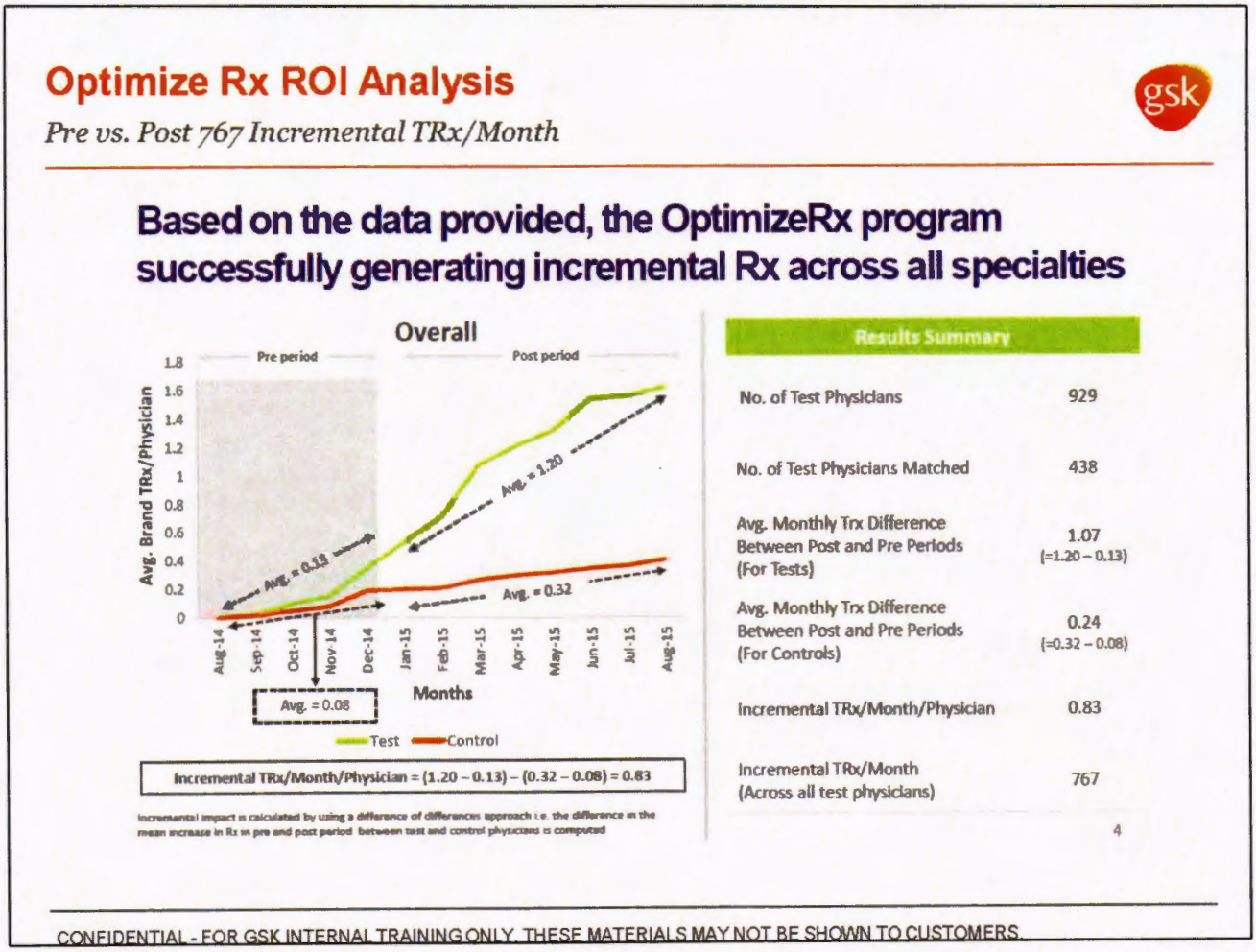
168. OptimizeRx was so confident in the ability of its financial messaging campaign to increase prescriptions of the sponsored drug, that it offered to guarantee an ROI of 1:1. In other words, if GSK agreed to invest $150,000 and run the program for 6 months, OptimizeRx would guarantee a return of $150,000.

169. OptimizeRx offered that it could target particular prescribers but that its recommendation was to "provide visibility of the savings offer to all HCPs within the EHR workflow to maximize the program performance and reach and ultimately drive the best return."

170. OptimizeRx pitched that a third party analysis found the average ROI of the program to be 5:1. It went on to provide extensive analysis showing that the financial messaging program "successfully generat[ed] incremental Rx fill across all specialties," "across all

regions," and that the promotional impact was "seen highest across high value market segment prescribers." Overall, "EHR Financial Messaging Program yielded over 600% ROI."

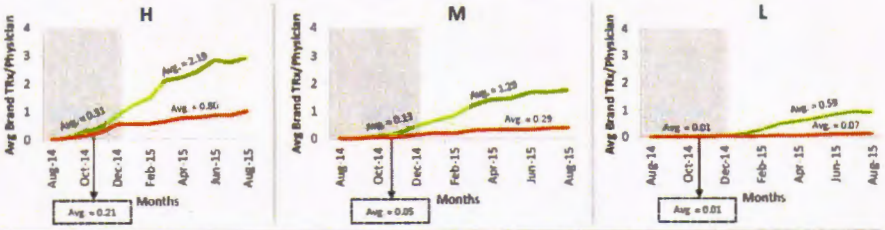


Optimize Rx ROI Analysis

Include H, M, & Lo Deciles in Test – 207 Incremental Lifts in Lo Segment

Promotional impact seen highest across high value market segment prescribers

Test and Control TRx Trend by Market Volume — Test — Control



Market Segment	Number of Test Physician: Total	Number of Test Physician: Matched	Avg. Monthly TRx Difference Between Post and Pre Periods: Test	Avg. Monthly TRx Difference Between Post and Pre Periods: Control	Impact (Monthly): Incremental TRx/Doc	Impact (Monthly): % Change*	Impact (Monthly): Incremental TRx
H	235	100	1.88	0.59	1.29	218%	302
M	282	133	1.16	0.24	0.92	379%	258
L	401	205	0.58	0.06	0.52	855%	207
Unknown	11	NA	NA	NA	NA	NA	NA
Total	929	438	1.075	0.249	0.826	332%	767

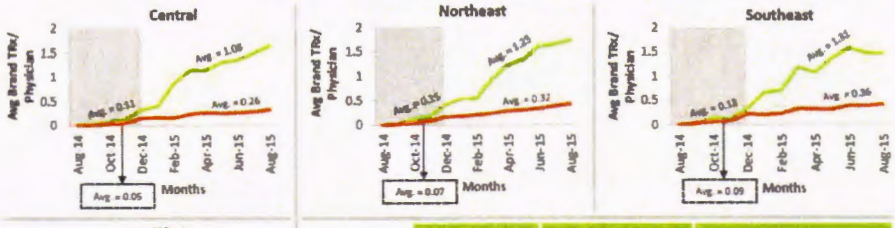
* % Change between difference of tests and difference of controls

Optimize Rx ROI Analysis

Regionality Is Also Reported

At a sub-geography level, impact is similar across all regions, though Southeast region has shown highest uptake.

Test and Control TRx Trend by Zone — Test — Control



Zone	Number of Test Physician: Total	Number of Test Physician: Matched	Avg. Monthly TRx Difference Between Post and Pre Periods Across: Test	Avg. Monthly TRx Difference Between Post and Pre Periods Across: Control	Impact (Monthly): Incremental TRx/Doc	Impact (Monthly): % Change*	Impact (Monthly): Incremental TRx
Central	204	92	0.97	0.21	0.76	366%	156
Northeast	215	99	1.08	0.25	0.83	336%	178
Southeast	238	117	1.18	0.27	0.91	335%	216
West	248	126	1.15	0.28	0.86	302%	214
Total	905	434	1.099	0.255	0.844	332%	764

* % Change between difference of tests and difference of controls

Note: Zones determined from PCP alignment. A total of 24 HCPs did not have any region assigned in the alignment received.

Optimize Rx ROI Analysis

Risk Share is Offered and our investment will be matched 1:1

EHR Financial Messaging Program yielded over 600% ROI

- Brand was able to see the overall incremental revenue of the promotional campaign
- ROI Cost calculation:
  - Includes the program cost
  - Cost of the EHR coupon redemptions
  - Incremental revenue program generated through brand script lift
  - Utilizing 60% gross margin

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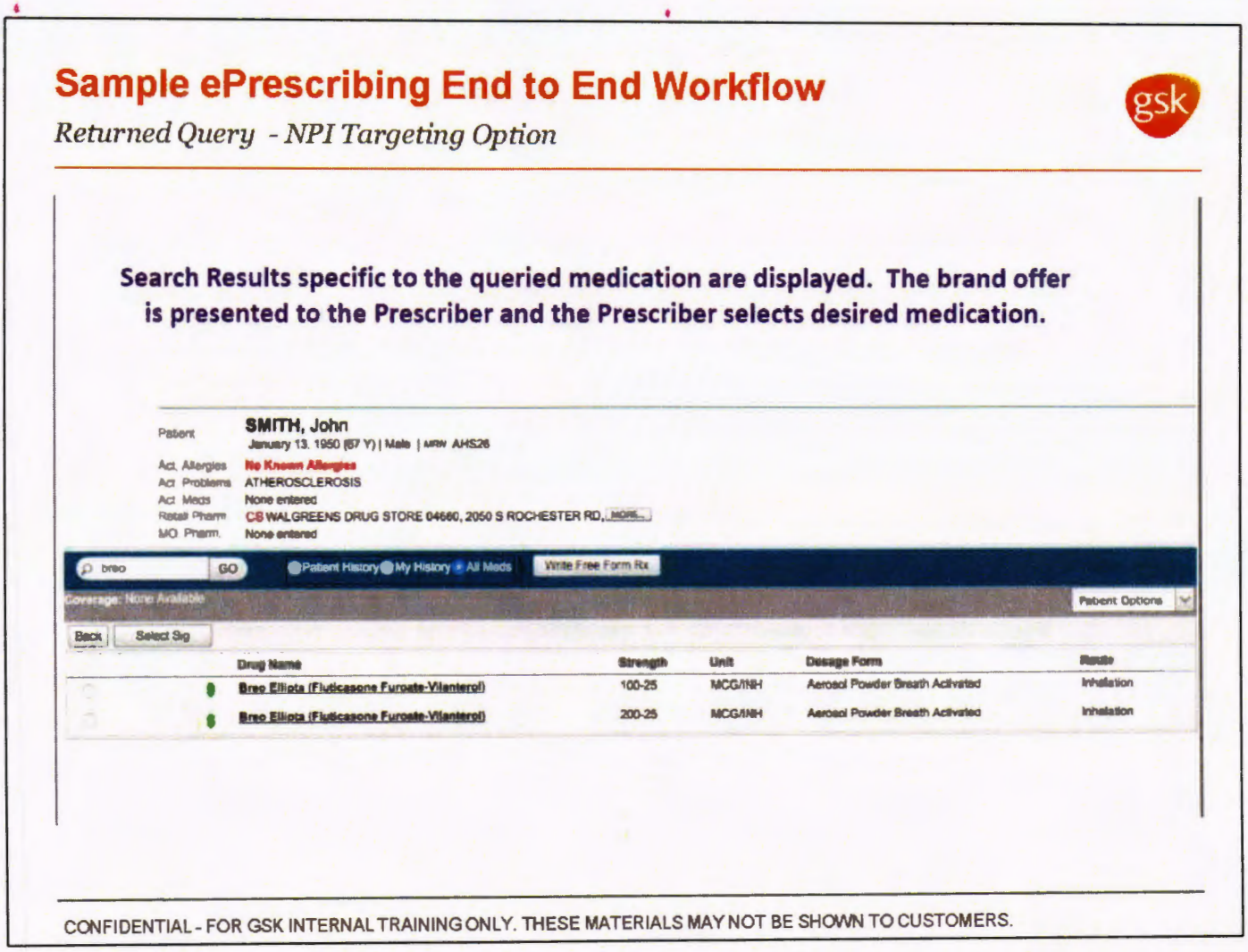
171. OptimizeRx went on to provide a sample workflow for the financial messaging program. The process would work as follows. The prescriber would search for the medication they wished to prescribe. Search results would display and the "brand offer" in the form of a "green dollar sign" would appear next to the drug names to which it applied.



172. The prescriber would then process the script and send the savings offer to the pharmacy. The prescriber would have the option to view the savings offer by clicking on an active eCoupon hyperlink. When the prescriber sent the prescription to the pharmacy, OptimizeRx would send the relevant offer codes and processing instructions to the pharmacy along with the electronic prescription.

173. The full coupon would include a disclaimer that it was limited to "eligible commercially insured patients." However, the financial messaging appeared for all targeted prescribers and all patients, regardless of eligibility constraints.

174. OptimizeRx's "standard pricing structure" for a financial messaging program included a program set-up fee of $25,000, a monthly management fee of $2,000, and $4-$5 every time the "financial message" (i.e., green dollar sign) appeared in a provider's search.

175. Even though GSK declined use of this program, Relator Bay understands that these programs are well utilized by other pharma companies and brands. Payments from pharma companies to EHRs, brokered through OptimizeRx, to arrange for the prescribing of the pharma companies' prescription medications, constitute the payment of illegal remuneration in violation of the Anti-Kickback Statute and result in the submission of false and fraudulent claims to federal and state programs.

v. AllScripts

176. AllScripts is a publicly-traded EHR and health IT company, headquartered in Chicago. In 2018, AllScripts acquired Practice Fusion, a cloud-based EHR, but also had its own suite of products including TouchWorks EHR, designed for larger single and multispecialty practices, and Professional EHR, for small to mid-sized physician practices.

177. In 2017/2018, GSK's respiratory franchise entered into an arrangement with AllScripts to develop clinical intervention tools in its EHRs to "drive awareness about asthma care by displaying clinically relevant recommendations." This was known as the "CareInsights" program. This campaign was unusual in that GSK partnered directly with AllScripts (the EHR company) rather than with an aggregator or consultant. In addition, the campaign appears not to have been promoting any particular GSK drug. Rather, the project was intended to "[c]ontinue to reinforce GSK's leadership position in Respiratory Care."

178. The AllScripts awareness campaign consisted of a series of alerts based on the severity of a patient's asthma disease state to guide providers toward prescribing one of GSK's branded respiratory products. In return for payment, AllScripts agreed to provide a number of program deliverables, including enrolling providers using its systems and targeting a list of providers identified by GSK.

179. The AllScripts program was reported to be "highly successful" on a number of metrics including that "providers are taking action at a top rate" with 20% of "recommendations" resolved by providers and a 5% resolution rate across the board. In addition, AllScripts reported to GSK that, as a result of the CDS tool, "40% of doctors took action to step up therapy when control of inflammation and bronchoconstriction is recommended per the guidelines."

180. The GSK program purported to "deliver point of care asthma treatment recommendations for initiating asthma therapy" based on NIH Guidelines but "does not take into account consideration alternative therapies, options for stepping up/down based on control, or treatment of acute asthma exacerbations."

181. AllScripts described its CareInsight Programs as "designed to assist clinicians in their efforts to close certain 'gaps' in a patient's care, based on evidence-based guidelines for optimal patient care." AllScripts claimed that "[t]hese programs do not attempt to influence or encourage the use of any particular brand or drug or particular drug product, and recommendations are created from respected, third party clinical guidelines that are designed to enhance clinical decisions and make it easier for a clinician to obtain these recommendations within their existing workflow." However, despite claiming not to promote particular brands or drugs, the program does not allow for reference to GSK competitor's products.

182. AllScripts provided GSK with information about how many providers and prescriptions were generated from its EHR platforms – AllScripts Professional EHR and AllScripts TouchWorks. It also promised "effectiveness reporting" to document "if the recommendation resulted in an increase in the behavior recommended by the recommendation." Rather than refer to referrals as referrals, the AllScripts materials talk about "resolution of recommendations for treatment in favor of the recommendation and utilization." One August 2017 email from an AllScripts Product Delivery Manager to Relator notes that "we are . . . showing an 8% resolutions rate (resolutions/ fires) which is also phenomenal utilization."

183. From the GSK side, ensuring disease education may have been one, but only one, goal of the program. Rather, GSK was laser focused on assessing the impact on prescribing and only would pay for the intervention if AllScripts could document that the digital interventions in the EHR workflows had resulted in increased prescribing of GSK products – so called, "script lift analysis." Script Lift reports measured increases in providers prescribing, scripts, and patients receiving scripts.

184. GSK required, and AllScripts offered, to provide data on exactly those metrics before, during and after the respiratory guidelines digital intervention program.

[redacted]

From: [redacted]
Sent: Friday, August 18, 2017 2:01 PM
To: [redacted]
Cc: [redacted]
Subject: GSK CareInsights: High Level Summary of July 2017
Attachments: GSKMonthlyEnrollment_July2017.xlsx; July 2017 GSKMonthly Interaction Report.xlsx

EXTERNAL

Hi [redacted],

As promised, please find our High Level Summary below.

We have utilized both the enrollment and interaction reports attached for our summary.

We can see that the initial approach to recruiting allowed us to enroll 30 practices representing 4384 for July. It's especially of note that a large practice was enthusiastic about participating in the program!

Our program expectations:

- The interaction data encompasses those providers with data rights, while the enrollment report encompasses all providers.
- All providers in the large practice recruited at the end of July may not use this program or may use it at a lesser rate than those with asthma specialties. The large practice encompasses multiple specialties, so this is typical behavior.
- We will gain additional visibility to the impact for providers in that large practice in August interaction reports (as the large practice only had 3 days of interaction for the month of July).
- August reports will become available mid-September.
- Alerts are fired to all enrolled providers for all eligible patients. We are unable to actively unenroll providers or control the frequency of fires.
- This CareInsights program is meant to drive awareness about asthma care by displaying clinically relevant recommendations. Whether the recommendations are resolved or not, this program brings patient care to the top of mind through GSK's sponsorship!

Key Findings:

- With only 2 months into the program, we have a significant amount of providers enrolled. Of the 10+ CareInsights projects we have initiated thus far, we have never seen this type of growth in such a short time!
- More than 50% of the Providers currently enrolled in the Program are in the Primary Care or Pulmonology Specialty. Our recruitment team was able to focus on gathering relevant providers to this program.
- Of the 918 recommendations fired (as per the transactional number we sent for billing), 52 (6%) of these alerts are applicable towards providers with data rights. The remainder is applicable for providers without data rights.
- We are also showing an 8% resolution rate (resolutions/fires), which is also phenomenal utilization.
- Once August reports are available (mid-September), 3 reporting cycles remain to provide data. If GSK wishes to return to proactive recruitment efforts, we'll see an even greater uptick of interaction data.

As we look towards September and the opportunity to gain visibility further into the impact of the initial recruitment efforts, we will continue to support you with information that you may need to make decisions around restarting proactive recruitment efforts and adjusting budgeting needs.

1

3. Defendants Carefully Track and Analyze "Return on Investment" from Intervention Based on Increased Prescribing of Branded Drug or Vaccine

185. The purpose of the digital interventions is to induce prescribing. Pharma companies and the EHR aggregators track and measure "increase[s] in providers prescribing, increase[s] in scripts, [and] increase[s] [in] patients receiving scripts (before, during and after [implementation of intervention])." "The unit of analysis is the individual prescriber. The primary outcome of the analysis is the number of prescriptions filled per prescriber per month[.]"

186. Although there are acknowledged limitations in the data exchanged, all involved understand that the purpose of the programs is to achieve "script lift" and that the sponsoring pharma company pays for these programs to obtain a deliverable that "test[s] the statistical significance of the lift" derived from the digital intervention.

187. Statements of work are for limited periods. ROI will be evaluated by pharma when deciding whether to proceed with additional payments to the EHR or EHR aggregator/consultant. By accepting these payments, the EHRs and EHR aggregators/consultants understand that they have assumed responsibility for delivering patients to the pharma brand.

B. Violations of AKS are Per Se Material Violations of the False Claims Act as a Matter of Law

188. Defendants' conduct is a brazen violation of the Anti-Kickback Statute ("AKS"), 42 U.S.C. § 1320a-7b(b), which makes it illegal to offer remuneration to induce referrals of business payable, in whole or in part, by federal healthcare programs.

189. As a result of this scheme to pay illegal remuneration to EHRs for digital interventions in clinical workflows to induce increased prescribing of sponsored products, federal and state health programs, including Medicare and Medicaid, have paid many millions of dollars in claims for prescription drugs not eligible for reimbursement.

190. Violations of the AKS are material to payment under the FCA as a matter of law. Each prescription written for a federal program beneficiary obtained as part of an illegal

kickback scheme is a false or fraudulent claim within the meaning of the federal False Claims Act and analogous state statues.

Count I
Federal False Claims Act
31 U.S.C. §§ 3729(a)(1)(A)–(B)

191. Relator repeats and realleges each and every allegation set forth above as though fully set forth herein.

192. This is a claim for treble damages and penalties under the False Claims Act, 31 U.S.C. § 3729, et seq., as amended.

193. By virtue of the acts described above, defendants knowingly presented or caused to be presented, false or fraudulent claims to officers, employees or agents of the United States Government for payment or approval under Medicaid, Medicare and various other government health care programs, within the meaning of 31 U.S.C. § 3729(a)(1)(A).

194. By virtue of the acts described above, defendants knowingly made, used, or caused to be made or used false or fraudulent records and statements, and omitted material facts, to get false and fraudulent claims paid or approved under Medicaid, Medicare and various other government health care programs, within the meaning of 31 U.S.C. § 3729(a)(1)(B).

195. The United States, unaware of the falsity of the records, statements and claims made or caused to be made by the defendants, paid and continues to pay the claims that would not be paid but for defendants' unlawful conduct.

196. By reason of the defendants' acts, the United States has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

197. Additionally, the United States is entitled to the maximum penalty for each and every false and fraudulent claim made and caused to be made by defendant arising from their unlawful conduct as described herein.

Count II
California False Claims Act
Cal. Gov't Code § 12650 *et seq.*

198. Relator repeats and realleges each and every allegation set forth above as though fully set forth herein.

199. This is a claim for treble damages and penalties under the California False Claims Act.

200. By virtue of the acts described above, defendants knowingly presented or caused to be presented, false or fraudulent claims to the California State Government for payment or approval.

201. By virtue of the acts described above, defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the California State Government to approve and pay such false and fraudulent claims.

202. The California State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by defendants, paid and continues to pay the claims that would not be paid but for defendants' unlawful conduct.

203. By reason of the defendants' acts, the State of California has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

204. Additionally, the California State Government is entitled to the maximum penalty for each and every violation alleged herein.

Count III
Colorado False Claims Act
Colo. Rev. Stat. § 25.5-4-303.5 *et seq.*

205. Relator repeats and realleges each and every allegation set forth above as though fully set forth herein.

206. This is a claim for treble damages and penalties under the Colorado False Claims Act.

207. By virtue of the acts described above, defendants knowingly presented or caused to be presented, false or fraudulent claims to the Colorado State Government for payment or approval.

208. By virtue of the acts described above, defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Colorado State Government to approve and pay such false and fraudulent claims.

209. The Colorado State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by defendants, paid and continues to pay the claims that would not be paid but for defendants' unlawful conduct.

210. By reason of the defendants' acts, the State of Colorado has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

211. Additionally, the Colorado State Government is entitled to the maximum penalty for each and every violation alleged herein.

Count IV
Connecticut False Claims Act
Conn. Gen. Stat. § 4-274 *et seq.*

212. Relator repeats and realleges each and every allegation set forth above as though fully set forth herein.

213. This is a claim for treble damages and penalties under the Connecticut False Claims and Reporting Act.

214. By virtue of the acts described above, defendants knowingly presented or caused to be presented, false or fraudulent claims to the Connecticut State Government for payment or approval.

215. By virtue of the acts described above, defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Connecticut State Government to approve and pay such false and fraudulent claims.

216. The Connecticut State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by defendants, paid and continues to pay the claims that would not be paid but for defendants' unlawful conduct.

217. By reason of the defendants' acts, the State of Connecticut has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

218. Additionally, the Connecticut State Government is entitled to the maximum penalty for each and every violation alleged herein.

Count V
Delaware False Claims and Reporting Act
6 Del C. § 1201 *et seq.*

219. Relator repeats and realleges each and every allegation set forth above as though fully set forth herein.

220. This is a claim for treble damages and penalties under the Delaware False Claims and Reporting Act.

221. By virtue of the acts described above, defendants knowingly presented or caused to be presented, false or fraudulent claims to the Delaware State Government for payment or approval.

222. By virtue of the acts described above, defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Delaware State Government to approve and pay such false and fraudulent claims.

223. The Delaware State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by defendants, paid and continues to pay the claims that would not be paid but for defendants' unlawful conduct.

224. By reason of the defendants' acts, the State of Delaware has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

225. Additionally, the Delaware State Government is entitled to the maximum penalty for each and every violation alleged herein.

Count VI
District of Columbia False Claims Law
D.C. Code Ann. § 2-381.01 *et seq.*

226. Relator repeats and realleges each and every allegation set forth above as though fully set forth herein.

227. This is a claim for treble damages and penalties under the District of Columbia Procurement Reform Amendment Act.

228. By virtue of the acts described above, defendants knowingly presented or caused to be presented, false or fraudulent claims to the District of Columbia Government for payment or approval.

229. By virtue of the acts described above, defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the District of Columbia Government to approve and pay such false and fraudulent claims.

230. The District of Columbia Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by defendants, paid and continues to pay the claims that would not be paid but for defendants' defective laboratory tests, unnecessary treatments and surgeries, and/or illegal inducements and business practices.

231. By reason of the defendants' acts, the District of Columbia has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

232. The District of Columbia is entitled to the maximum penalty for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by defendants.

Count VII
Florida False Claims Act
Fla. Stat. Ann. § 68.081 *et seq.*

233. Relator repeats and realleges each and every allegation set forth above as though fully set forth herein.

234. This is a claim for treble damages and penalties under the Florida False Claims Act.

235. By virtue of the acts described above, defendants knowingly presented or caused to be presented, false or fraudulent claims to the Florida State Government for payment or approval.

236. By virtue of the acts described above, defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Florida State Government to approve and pay such false and fraudulent claims.

237. The Florida State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by defendant, paid and continues to pay the claims that would not be paid but for defendants' unlawful conduct.

238. By reason of the defendants' acts, the State of Florida has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

239. Additionally, the Florida State Government is entitled to the maximum penalty for each and every violation alleged herein.

Count VIII
Georgia State False Medicaid Claims Act
Ga. Code Ann. § 49-4-168 *et seq.*

240. Relator repeats and realleges each and every allegation set forth above as though fully set forth herein.

241. This is a claim for treble damages and penalties under the Georgia State False Medicaid Claims Act.

242. By virtue of the acts described above, defendants knowingly presented or caused to be presented, false or fraudulent claims to the Georgia State Government for payment or approval.

243. By virtue of the acts described above, defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Georgia State Government to approve and pay such false and fraudulent claims.

244. The Georgia State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by defendant, paid and continues to pay the claims that would not be paid but for defendants' unlawful conduct.

245. By reason of the defendants' acts, the State of Georgia has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

246. Additionally, the Georgia State Government is entitled to the maximum penalty for each and every violation alleged herein.

Count IX
Hawaii False Claims Act
Haw. Rev. Stat. § 661-21 *et seq.*

247. Relator repeats and realleges each and every allegation set forth above as though fully set forth herein.

248. This is a claim for treble damages and penalties under the Hawaii False Claims Act.

249. By virtue of the acts described above, defendants knowingly presented or caused to be presented, false or fraudulent claims to the Hawaii State Government for payment or approval.

250. By virtue of the acts described above, defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Hawaii State Government to approve and pay such false and fraudulent claims.

251. The Hawaii State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by defendant, paid and continues to pay the claims that would not be paid but for defendants' unlawful conduct.

252. By reason of the defendants' acts, the State of Hawaii has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

253. Additionally, the Hawaii State Government is entitled to the maximum penalty of for each and every violation alleged herein.

Count X
Illinois False Claims Act
740 Ill. Comp. Stat. § 175/1 *et seq.*

254. Relator repeats and realleges each and every allegation set forth above as though fully set forth herein.

255. This is a claim for treble damages and penalties under the Illinois Whistleblower Reward and Protection Act.

256. By virtue of the acts described above, defendants knowingly presented or caused to be presented, false or fraudulent claims to the Illinois State Government for payment or approval.

257. By virtue of the acts described above, defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Illinois State Government to approve and pay such false and fraudulent claims.

258. The Illinois State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by defendant, paid and continues to pay the claims that would not be paid but for defendants' unlawful conduct.

259. By reason of the defendants' acts, the State of Illinois has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

260. Additionally, the Illinois State Government is entitled to the maximum penalty for each and every violation alleged herein.

Count XI
Indiana Medicaid False Claims and Whistleblower Protection Act
Ind. Code Ann. §§ 5-11-5.7 *et seq.*

261. Relator repeats and realleges each and every allegation set forth above as though fully set forth herein.

262. This is a claim for treble damages and penalties under the Indiana Medicaid False Claims and Whistleblower Protection Act.

263. By virtue of the acts described above, defendants knowingly presented or caused to be presented, false or fraudulent claims to the Indiana State Government for payment or approval.

264. By virtue of the acts described above, defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Indiana State Government to approve and pay such false and fraudulent claims.

265. The Indiana State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by defendant, paid and continues to pay the claims that would not be paid but for defendants' unlawful conduct.

266. By reason of the defendants' acts, the State of Indiana has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

267. Additionally, the Indiana State Government is entitled to the maximum civil penalty for each and every violation alleged herein.

Count XII
Iowa False Claims Act
Iowa Code Ann. §685.1 *et seq.*

268. Relator repeats and realleges each and every allegation set forth above as though fully set forth herein.

269. This is a claim for treble damages and penalties under the Iowa False Claims Act.

270. By virtue of the acts described above, defendants knowingly presented or caused to be presented, false or fraudulent claims to the Iowa State Government for payment or approval.

271. By virtue of the acts described above, defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Iowa State Government to approve and pay such false and fraudulent claims.

272. The Iowa State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by defendant, paid and continues to pay the claims that would not be paid but for defendants' unlawful conduct.

273. By reason of the defendants' acts, the State of Iowa has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

274. Additionally, the Iowa State Government is entitled to the maximum penalty for each and every violation alleged herein.

Count XIII
Louisiana Medical Assistance Programs Integrity Law
La. Rev. Stat. § 437:437.1 *et seq.*

275. Relator repeats and realleges each and every allegation set forth above as though fully set forth herein.

276. This is a claim for treble damages and penalties under the Louisiana Medical Assistance Programs Integrity Law.

277. By virtue of the acts described above, defendants knowingly presented or caused to be presented, false or fraudulent claims to the Louisiana State Government for payment or approval.

278. By virtue of the acts described above, defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Louisiana State Government to approve and pay such false and fraudulent claims.

279. The Louisiana State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by defendant, paid and continues to pay the claims that would not be paid but for defendants' unlawful conduct.

280. By reason of the defendants' acts, the State of Louisiana has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

281. Additionally, the Louisiana State Government is entitled to the maximum penalty for each and every violation alleged herein.

Count XIV
Maryland False Health Claims Act
Md. Code Ann., Health-Gen. § 2-601 *et seq.*

282. Relator repeats and realleges each and every allegation set forth above as though fully set forth herein.

283. This is a claim for treble damages and penalties under the Maryland False Health Claims Act.

284. By virtue of the acts described above, defendants knowingly presented or caused to be presented, false or fraudulent claims to the Maryland State Government for payment or approval.

285. By virtue of the acts described above, defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Maryland State Government to approve and pay such false and fraudulent claims.

286. The Maryland State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by defendant, paid and continues to pay the claims that would not be paid but for defendants' unlawful conduct.

287. By reason of the defendants' acts, the State of Maryland has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

288. Additionally, the Maryland State Government is entitled to the maximum penalty for each and every violation alleged herein.

Count XV
Massachusetts False Claims Law
Mass. Gen. Laws ch. 12 § 5B *et seq.*

289. Relator repeats and realleges each and every allegation set forth above as though fully set forth herein.

290. This is a claim for treble damages and penalties under the Massachusetts False Claims Law.

291. By virtue of the acts described above, defendants knowingly presented or caused to be presented, false or fraudulent claims to the Massachusetts State Government for payment or approval.

292. By virtue of the acts described above, defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Massachusetts State Government to approve and pay such false and fraudulent claims.

293. The Massachusetts State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by defendant, paid and continues to pay the claims that would not be paid but for defendants' unlawful conduct.

294. By reason of the defendants' acts, the State of Massachusetts has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

295. Additionally, the Massachusetts State Government is entitled to the maximum penalty for each and every violation alleged herein.

Count XVI
Michigan Medicaid False Claims Act
Mich. Comp. Laws Ann. § 400.601 *et seq.*

296. Relator repeats and realleges each and every allegation set forth above as though fully set forth herein.

297. This is a claim for treble damages and penalties under the Michigan Medicaid False Claims Act.

298. By virtue of the acts described above, defendants knowingly presented or caused to be presented, false or fraudulent claims to the Michigan State Government for payment or approval.

299. By virtue of the acts described above, defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Michigan State Government to approve and pay such false and fraudulent claims.

300. The Michigan State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by defendant, paid and continues to pay the claims that would not be paid but for defendants' unlawful conduct.

301. By reason of the defendants' acts, the State of Michigan has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

302. Additionally, the Michigan State Government is entitled to the maximum penalty for each and every violation alleged herein.

Count XVII
Minnesota False Claims Act
Minn. Stat. Ann. § 15C.01 *et seq.*

303. Relator repeats and realleges each and every allegation set forth above as though fully set forth herein.

304. This is a claim for treble damages and penalties under the Minnesota False Claims Act.

305. By virtue of the acts described above, defendants knowingly presented or caused to be presented, false or fraudulent claims to the Minnesota State Government for payment or approval.

306. By virtue of the acts described above, defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Minnesota State Government to approve and pay such false and fraudulent claims.

307. The Minnesota State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by defendant, paid and continues to pay the claims that would not be paid but for defendants' unlawful conduct.

308. By reason of the defendants' acts, the State of Minnesota has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

309. Additionally, the Minnesota State Government is entitled to the maximum penalty for each and every violation alleged herein.

Count XVIII
Montana False Claims Act
Mont. Code Ann. § 17-8-401 *et seq.*

310. Relator repeats and realleges each and every allegation set forth above as though fully set forth herein.

311. This is a claim for treble damages and penalties under the Montana False Claims Act.

312. By virtue of the acts described above, defendants knowingly presented or caused to be presented, false or fraudulent claims to the Montana State Government for payment or approval.

313. By virtue of the acts described above, defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Montana State Government to approve and pay such false and fraudulent claims.

314. The Montana State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by defendant, paid and continues to pay the claims that would not be paid but for defendants' unlawful conduct.

315. By reason of the defendants' acts, the State of Montana has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

316. Additionally, the Montana State Government is entitled to the maximum penalty for each and every violation alleged herein.

Count XIX
Nevada False Claims Act
Nev. Rev. Stat. Ann. § 357.040 *et seq.*

317. Relator repeats and realleges each and every allegation set forth above as though fully set forth herein.

318. This is a claim for treble damages and penalties under the Nevada False Claims Act.

319. By virtue of the acts described above, defendants knowingly presented or caused to be presented, false or fraudulent claims to the Nevada State Government for payment or approval.

320. By virtue of the acts described above, defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Nevada State Government to approve and pay such false and fraudulent claims.

321. The Nevada State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by defendant, paid and continues to pay the claims that would not be paid but for defendants' unlawful conduct.

322. By reason of the defendants' acts, the State of Nevada has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

323. Additionally, the Nevada State Government is entitled to the maximum penalty for each and every violation alleged herein.

Count XX
New Jersey False Claims Act
N.J. Stat. § 2A:32C-1 *et seq.*

324. Relator repeats and realleges each and every allegation set forth above as though fully set forth herein.

325. This is a claim for treble damages and penalties under the New Jersey False Claims Act.

326. By virtue of the acts described above, defendants knowingly presented or caused to be presented, false or fraudulent claims to the New Jersey State Government for payment or approval.

327. By virtue of the acts described above, defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the New Jersey State Government to approve and pay such false and fraudulent claims.

328. The New Jersey State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by defendant, paid and continues to pay the claims that would not be paid but for defendants' unlawful conduct.

329. By reason of the defendants' acts, the State of New Jersey has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

330. Additionally, the New Jersey State Government is entitled to the maximum penalty for each and every violation alleged herein.

Count XXI
New Mexico Medicaid False Claims Act, N.M. Stat. Ann. § 27-14-1 *et seq.* and New Mexico Fraud Against Taxpayers Act, N.M. Stat. Ann. § 44-9-1 *et seq.*

331. Relator repeats and realleges each and every allegation set forth above as though fully set forth herein.

332. This is a claim for treble damages and penalties under the New Mexico Medicaid False Claims Act and the New Mexico Fraud Against Taxpayers Act.

333. By virtue of the acts described above, defendants knowingly presented or caused to be presented, false or fraudulent claims to the New Mexico State Government for payment or approval.

334. By virtue of the acts described above, defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the New Mexico State Government to approve and pay such false and fraudulent claims.

335. The New Mexico State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by defendant, paid and continues to pay the claims that would not be paid but for defendants' unlawful conduct.

336. By reason of the defendants' acts, the State of New Mexico has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

337. Additionally, the New Mexico State Government is entitled to the maximum penalty for each and every violation alleged herein.

Count XXII
New York False Claims Act
N.Y. State Fin. § 187 *et seq.*

338. Relator repeats and realleges each and every allegation set forth above as though fully set forth herein.

339. This is a claim for treble damages and penalties under the New York False Claims Act.

340. By virtue of the acts described above, defendants knowingly presented or caused to be presented, false or fraudulent claims to the New York State Government for payment or approval.

341. By virtue of the acts described above, defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the New York State Government to approve and pay such false and fraudulent claims.

342. The New York State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by

defendant, paid and continues to pay the claims that would not be paid but for defendants' unlawful conduct.

343. By reason of the defendants' acts, the State of New York has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

344. Additionally, the New York State Government is entitled to the maximum penalty for each and every violation alleged herein.

Count XXIII
North Carolina False Claims Act
N.C. Gen. Stat. § 1-605 et seq.

345. Relator repeats and realleges each and every allegation set forth above as though fully set forth herein.

346. This is a claim for treble damages and penalties under the North Carolina False Claims Act.

347. By virtue of the acts described above, defendants knowingly presented or caused to be presented, false or fraudulent claims to the North Carolina State Government for payment or approval.

348. By virtue of the acts described above, defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the North Carolina State Government to approve and pay such false and fraudulent claims.

349. The North Carolina State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by defendant, paid and continues to pay the claims that would not be paid but for defendants' unlawful conduct.

350. By reason of the defendants' acts, the State of North Carolina has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

351. Additionally, the North Carolina State Government is entitled to the maximum penalty for each and every violation alleged herein.

Count XXIV
Oklahoma Medicaid False Claims Act
63 Okl. St. § 5053

352. Relator repeats and realleges each and every allegation set forth above as though fully set forth herein.

353. This is a claim for treble damages and penalties under the Oklahoma Medicaid False Claims Act.

354. By virtue of the acts described above, defendants knowingly presented or caused to be presented, false or fraudulent claims to the Oklahoma State Government for payment or approval.

355. By virtue of the acts described above, defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Oklahoma State Government to approve and pay such false and fraudulent claims.

356. The Oklahoma State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by defendant, paid and continues to pay the claims that would not be paid but for defendants' unlawful conduct.

357. By reason of the defendants' acts, the State of Oklahoma has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

358. Additionally, the Oklahoma State Government is entitled to the maximum civil penalty for each and every violation alleged herein.

Count XXV
Rhode Island False Claims Act
R.I. Gen. Laws § 9-1.1-1 *et seq.*

359. Relator repeats and realleges each and every allegation set forth above as though fully set forth herein.

360. This is a claim for treble damages and penalties under the Rhode Island False Claims Act.

361. By virtue of the acts described above, defendants knowingly presented or caused to be presented, false or fraudulent claims to the Rhode Island State Government for payment or approval.

362. By virtue of the acts described above, defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Rhode Island State Government to approve and pay such false and fraudulent claims.

363. The Rhode Island State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by defendant, paid and continues to pay the claims that would not be paid but for defendants' unlawful conduct.

364. By reason of the defendants' acts, the State of Rhode Island has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

365. Additionally, the Rhode Island State Government is entitled to the maximum civil penalty for each and every violation alleged herein.

Count XXVI
Tennessee Medicaid False Claims Act
Tenn. Code Ann. § 71-5-181 *et seq.*

366. Relator repeats and realleges each and every allegation set forth above as though fully set forth herein.

367. This is a claim for treble damages and penalties under the Tennessee Medicaid False Claims Act.

368. By virtue of the acts described above, defendants knowingly presented or caused to be presented, false or fraudulent claims to the Tennessee State Government for payment or approval.

369. By virtue of the acts described above, defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Tennessee State Government to approve and pay such false and fraudulent claims.

370. The Tennessee State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by defendant, paid and continues to pay the claims that would not be paid but for defendants' unlawful conduct.

371. By reason of the defendants' acts, the State of Tennessee has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

372. Additionally, the Tennessee State Government is entitled to the maximum penalty for each and every violation alleged herein.

Count XXVII
Texas Medicaid Fraud Prevention Act
Tex. Hum. Res. Code Ann. § 36.001 *et seq.*

373. Relator repeats and realleges each and every allegation set forth above as though fully set forth herein.

374. This is a claim for treble damages and penalties under the Texas Medicaid Fraud Prevention Act.

375. By virtue of the acts described above, defendants knowingly presented or caused to be presented, false or fraudulent claims to the Texas State Government for payment or approval.

376. By virtue of the acts described above, defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Texas State Government to approve and pay such false and fraudulent claims.

377. The Texas State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by defendant, paid and continues to pay the claims that would not be paid but for defendants' unlawful conduct.

378. By reason of the defendants' acts, the State of Texas has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

379. Additionally, the Texas State Government is entitled to the maximum penalty for each and every violation alleged herein.

Count XXVIII
Vermont False Claims Act
Vt. Stat. Ann. tit. 32, § 630 *et seq.*

380. Relator repeats and realleges each and every allegation set forth above as though fully set forth herein.

381. This is a claim for treble damages and penalties under the Vermont False Claims Act.

382. By virtue of the acts described above, defendants knowingly presented or caused to be presented, false or fraudulent claims to the Vermont State Government for payment or approval.

383. By virtue of the acts described above, defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Vermont State Government to approve and pay such false and fraudulent claims.

384. The Vermont State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by defendant, paid and continues to pay the claims that would not be paid but for defendants' unlawful conduct.

385. By reason of the defendants' acts, the State of Vermont has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

386. Additionally, the Vermont State Government is entitled to the maximum penalty for each and every violation alleged herein.

Count XXIX
Virginia Fraud Against Taxpayers Act
Va. Code Ann. § 8.01-216.3 *et seq.*

387. Relator repeats and realleges each and every allegation set forth above as though fully set forth herein.

388. This is a claim for treble damages and penalties under the Virginia Fraud Against Taxpayers Act.

389. By virtue of the acts described above, defendants knowingly presented or caused to be presented, false or fraudulent claims to the Virginia State Government for payment or approval.

390. By virtue of the acts described above, defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Virginia State Government to approve and pay such false and fraudulent claims.

391. The Virginia State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by defendant, paid and continues to pay the claims that would not be paid but for defendants' unlawful conduct.

392. By reason of the defendants' acts, the State of Virginia has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

393. Additionally, the Virginia State Government is entitled to the maximum penalty for each and every violation alleged herein.

Count XXX
Washington Medicaid False Claims Act
RCW 74.66 *et seq.*

394. Relator repeats and realleges each and every allegation set forth above as though fully set forth herein.

395. This is a claim for treble damages and penalties under the Washington Medicaid False Claims Act.

396. By virtue of the acts described above, defendants knowingly presented or caused to be presented, false or fraudulent claims to the Washington State Government for payment or approval.

397. By virtue of the acts described above, defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Washington State Government to approve and pay such false and fraudulent claims.

398. The Washington State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by defendant, paid and continues to pay the claims that would not be paid but for defendants' unlawful conduct.

399. By reason of the defendants' acts, the State of Washington has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

400. Additionally, the Washington State Government is entitled to the maximum penalty for each and every violation alleged herein.

Count XXXI
DOE States' False Claims Acts That Have Not Been Enacted or Are Not Effective at the Time of Filing

401. Relator repeats and realleges each and every allegation set forth above as though fully set forth herein.

402. This is a claim for treble damages and penalties against defendants under State False Claims Acts that are enacted subsequent to the filing of this Complaint, and which permit qui tam suits.

403. By virtue of the acts described above, defendants knowingly presented or caused to be presented, false or fraudulent claims to each of the States listed above.

404. By virtue of the acts described above, defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the States listed above to approve and pay such false and fraudulent claims.

405. The State Governments of each of the States listed above, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or

presented by defendant, paid and continues to pay the claims that would not be paid but for defendants' unlawful conduct.

406. By reason of defendants' acts, the States listed above have been damaged and continue to be damaged in substantial amounts to be determined at trial.

407. The State Governments of each of the States listed above are entitled to the maximum penalty for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by defendant.

PRAYER

WHEREFORE, Relators pray for judgment against the defendants as follows:

408. That defendants cease and desist from violating 31 U.S.C. § 3729 *et seq.*, and the counterpart provisions of the state statutes set forth above;

409. That this Court enter judgment against defendants in an amount equal to three times the amount of damages the United States and the Plaintiff States have sustained because of defendants' actions, plus a civil penalty for each violation of 31 U.S.C. § 3729 and the equivalent provisions of the state statutes set forth above;

410. That Relator be awarded the maximum amount allowed pursuant to § 3730(d) of the False Claims Act, and the equivalent provisions of the state statutes set forth above;

411. That Relator be awarded all costs of this action, including attorneys' fees and expenses; and

412. That Relator recover such other relief as the Court deems just and proper.

DEMAND FOR A JURY TRIAL

Pursuant to Rule 38 of the Federal Rules of Civil Procedure, Relator hereby demands a trial by jury.

Dated: February 4, 2022

DOWNS RACHLIN MARTIN PLLC

By: _____

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